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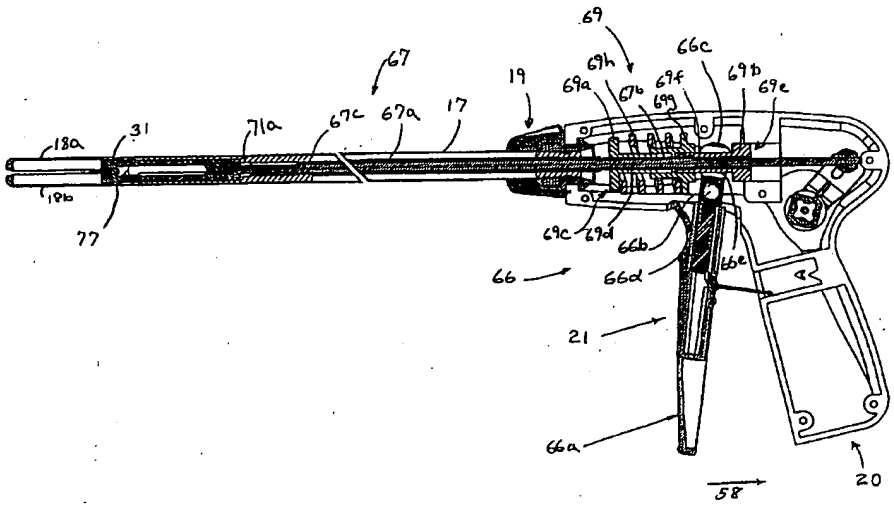

(57) Abstract: Medical devices, methods and systems for treating tissue are provided. An exemplary system comprises a fluid from a fluid from a fluid source at a fluid flow rate, a surgical device which provides power and the fluid to the tissue and a control mechanism which changes a fluid flow rate provided from the surgical device and changes a power level provided from the surgical device. The fluid flow rate changes between at least two-zero flow rates and the power level changes between at least two non-zero levels. An exemplary method comprises providing a fluid from a fluid source at a fluid flow rate, providing a surgical device which provides power and the fluid to the tissue, and changing the fluid flow rate of fluid provided from the surgical device with a change in power level provided from the surgical device.

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FLUID-ASSISTED MEDICAL DEVICES, FLUID DELIVERY SYSTEMS AND CONTROLLERS FOR SUCH DEVICES, AND METHODS

This application is being filed as a PCT International Patent application in the name of TissueLink Medical, Inc. (a U.S. national corporation), for the designation of all countries except the US, and Michael E. McClurken, David Lipson, Robert Luzzi, Arnold E. Oyola, Roger D. Greeley, and Mark T. Charbonneau (all US citizens), for the designation of the United States only, on 5 September 2002.

Field Of The Invention

This invention relates generally to the field of medical devices, methods and systems for use upon a body during surgery. More particularly, the invention relates to electrosurgical devices, methods and systems for use upon tissues of a human body during surgery.

Background

Electrosurgical devices use electrical energy, most commonly radio frequency (RF) energy, to cut tissue or to cauterize blood vessels. During use, a voltage gradient is created at the tip of the device, thereby inducing current flow and related heat generation in the tissue. With sufficiently high levels of electrical energy, the heat generated is sufficient to cut the tissue and, advantageously, to stop the bleeding from severed blood vessels.

Current electrosurgical devices can cause the temperature of tissue being treated to rise significantly higher than 100 °C, resulting in tissue desiccation, tissue sticking to the electrodes, tissue perforation, char formation and smoke generation. Peak tissue temperatures as a result of RF treatment of target tissue can be as high as 320 °C, and such high temperatures can be transmitted to adjacent tissue via thermal diffusion. Undesirable results of such transmission to adjacent tissue include unintended thermal damage to the tissue.

Using saline to couple RF electrical energy to tissue inhibits such undesirable effects as sticking, desiccation, smoke production and char formation. One key factor is inhibiting tissue desiccation, which occurs if tissue temperature exceeds 100 °C and all of the intracellular water boils away, leaving the tissue extremely dry and much less electrically conductive. However, an uncontrolled flow rate of saline can provide too much cooling at the electrode/tissue interface. This cooling reduces the temperature of the target tissue being treated, and the rate at which tissue thermal coagulation occurs is determined by tissue temperature. This, in turn, can result in longer treatment time, to achieve the desired tissue temperature for cauterization or

cutting of the tissue. Long treatment times are undesirable for surgeons since it is in the best interest of the patient, physician and hospital to perform surgical procedures as quickly as possible.

RF energy delivered to tissue is unpredictable and often not optimal when using general-purpose generators. Most general-purpose RF generators have modes for different waveforms (cut, coagulation, or a blend of these two) and device types (monopolar, bipolar), as well as power levels that can be set in watts. However, once these settings are chosen, the actual power delivered to tissue can vary dramatically over time as tissue impedance changes over the course of RF treatment. This is because the power delivered by most generators is a function of tissue impedance, with the power ramping down as impedance either decreases toward zero or increases significantly to several thousand ohms.

A further limitation of current electrosurgical devices arises from size constraints of the device in comparison to tissue that is encountered during a single surgical procedure. During the course of a single procedure, for example, a surgeon often encounters a wide variety of tissue sizes. Surgical devices often come in a variety of sizes because larger segments of tissue physically require commensurately larger electrode jaws or tips, but smaller segments of tissue often are not optimally treated by the much larger size RF device. It is undesirable to require numerous surgical devices during a single procedure, because this wastes valuable operating room time, can make it difficult to precisely relocate the treatment site, increases the risk of infection, and increases the cost by increasing the number of different surgical devices that are needed to complete the surgical procedure.

For example, a bipolar saline-enhanced tissue sealing forceps that has jaws long enough to effectively seal a 30 mm length of tissue may not be desirable for sealing a segment of tissue that is 10 mm in length. Excess saline from one of the electrode jaws (for a bipolar device) can flow to the other electrode in the space where there is no intervening tissue. This flow of electrically conductive saline can act as an electrical resistor in parallel with the electrical pathway through the target tissue. Electrical current flow through the saline can divert or shunt RF energy away from going through the target tissue, and slow down the rate at which the target tissue is heated and treated.

A surgeon may first be sealing and cutting lung tissue as part of a wedge resection using the full 30 mm jaw length 2 – 3 times to remove a tip of a lobe of lung for biopsy. If the intraoperative histopathology indicates that the suspected tissue has a malignant tumor, then the surgeon may convert the procedure to a lobectomy. As part of the lobectomy the surgeon will want to seal and cut large blood vessels that supply the lobe. Alternatively, the surgeon may want to toughen

up or coagulate large vessels with RF and then apply a ligating clip to assure hemostasis before cutting. Even compressed, these blood vessels might only fill a small fraction of the 30 mm length of electrode jaw. For at least the reasons identified above, this is an undesirable situation with current electrosurgical devices.

Summary of the Invention

In one exemplary embodiment, the invention provides a system for treating tissue comprising a power measurement device, a flow rate controller coupled to the power measurement device, and an electrosurgical device configured and arranged to provide radio frequency power and conductive fluid to the tissue, wherein the flow rate controller is configured and arranged to modify a flow rate of the conductive fluid to the tissue, based on signals from the power measurement device.

Preferably, the flow rate controller modifies the flow rate of the conductive fluid to the tissue based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. In a preferred embodiment, the flow rate controller modifies the flow rate of the conductive fluid to the tissue using the relationship:

$$Q = K \times P$$

where the flow rate **Q** is proportional to the power **P**, and where the proportionality constant **K** is given by:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

In another embodiment, the invention provides a device for modifying flow rate of conductive fluid to tissue based on measurement of radio frequency power delivered to the tissue. The device comprises a flow rate controller configured and arranged to modify flow rate of the conductive fluid to the tissue, based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. Preferably, the device modifies the flow rate of the conductive fluid to the tissue using the relationship:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

In an alternative embodiment, the invention provides a device for treating tissue using radio frequency power and conductive fluid. The device comprises a sensing device, and a processor coupled to the sensing device, wherein the processor

is configured and arranged to adjust the flow rate of the conductive fluid to the tissue, by determining a level of radio frequency power applied to the tissue using the sensing device, and adjusting the flow rate of the conductive fluid to the tissue. Preferably, the processor is configured and arranged to adjust the flow rate of the conductive fluid to the tissue based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. Preferably, the flow rate controller modifies the flow rate of the conductive fluid to the tissue using the relationship:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

In another embodiment, the invention provides a method for treating tissue comprising applying radio frequency power and conductive fluid to the tissue using a surgical device, wherein the conductive fluid is provided to the tissue at a fluid flow rate, determining an amount of radio frequency power applied to the tissue, and modifying the fluid flow rate based on the power applied to the tissue. Preferably, the step of modifying the fluid flow rate based on the power applied to the tissue comprises modifying the flow rate of the conductive fluid to the tissue based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. Preferably, the step of modifying the fluid flow rate based on the power applied to the tissue comprises determining the fluid flow rate using the relationship:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

In an alternative embodiment, the invention provides a method for treating tissue comprising providing a surgical device comprising an electrode, wherein the surgical device is configured and arranged to receive radio frequency power and conductive fluid and deliver the radio frequency power and conductive fluid to the tissue, determining the radio frequency power applied to the tissue, and providing the conductive fluid to the tissue at a fluid flow rate, wherein the fluid flow rate is modified to control boiling of the conductive fluid at the tissue. Preferably, the step of providing the conductive fluid to the tissue at a fluid flow rate comprises providing the conductive fluid to the tissue based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. In a preferred embodiment, the step of providing the conductive fluid to the tissue at a fluid flow rate comprises providing the conductive fluid to the tissue using the relationship:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

In another embodiment, the invention provides a system for treating tissue comprising a power measurement device, a flow rate controller coupled to the power measurement device, a flow control device coupled to the flow rate controller, and an electrosurgical device coupled to the flow control device and the power measurement device, wherein the electrosurgical device is configured and arranged to provide radio frequency power and conductive fluid to the tissue, and wherein the flow rate controller is configured and arranged to modify a flow rate of the conductive fluid to the electrosurgical device, based on signals from the power measurement device. Preferably, the flow control device comprises a pump. In one embodiment, the pump comprises a peristaltic pump. In another embodiment, the pump comprises a syringe pump. Preferably, the electrosurgical device comprises a bipolar electrosurgical device.

According to this embodiment, the flow rate controller is preferably configured and arranged to modify the flow rate of the conductive fluid to the flow control device based on heat used to warm the conductive fluid and heat used to convert the conductive fluid to vapor. In a preferred embodiment, the flow rate controller is configured and arranged to modify the flow rate of the conductive fluid to the tissue using the relationship:

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}}$$

The invention can improve the speed of tissue coagulation provided by fluid-enhanced electrosurgery by assuring that the electrode-tissue interface is within a desired temperature range (for example, not significantly hotter than 100 °C) through the control of the fraction of conductive fluid that is boiled off at the electrode-tissue interface. This improvement can be achieved by measuring power provided to the device and regulating the flow of fluid to the device. Preferably, tissue sensors (for example, that would measure tissue temperature or tissue impedance) are not required according to the invention.

Some embodiments of the invention can provide one or more advantages, such as the ability to achieve the desired tissue effect (for example, coagulation, cutting, or the like) in a fast, effective manner. The invention can also provide the ability to treat tissue quickly without using a tissue sensor (for example, a temperature sensor) built into the device or a custom special-purpose generator. The invention can allow a surgeon to use a variety of electrosurgical devices with a wide

variety of general-purpose generators. Further, the invention can provide the ability to use an electrosurgical device that is capable of quickly and effectively sealing a wide variety of tissue sizes and thicknesses.

In certain applications, a system for treating tissue is provided. The system comprises energy from energy source, a fluid from a fluid source, a surgical device which provides the energy and the fluid to the tissue and a fluid flow control mechanism which changes a flow rate of fluid provided from the surgical device with a change in a rate of energy provided from the surgical device. The flow rate of fluid changes between at least two non-zero flow rates, and the rate of energy changes between at least two non-zero rates of energy.

In some applications, the fluid flow control mechanism increases or decreases the flow rate of fluid with an increase or decrease in the rate of energy provided from the surgical device, respectively. Additionally or alternatively, the fluid flow control mechanism can increase or decrease the fluid flow rate linearly with an increase or decrease in the rate of energy provided from the surgical device, respectively.

In some applications, the energy provided from the surgical device leads to a heating of at least a portion of the fluid provided from the surgical device and the heating of the fluid results in a property change of at least a portion of the fluid. In some instances, the property change of the fluid comprises a color change due to dye present in the fluid, or a phase change from a liquid phase to a vapor phase. Additionally or alternatively, heating of the fluid results in vaporization of at least a portion of the fluid.

The energy provided from the surgical device generally leads to a heating of the tissue, and vaporization of the fluid provides a temperature control mechanism for the heating of the tissue. According to another aspect of the invention, the temperature control mechanism comprises the heat of vaporization of the fluid.

In some applications of the techniques described herein, the fluid flow control mechanism increases the flow rate of fluid provided from the surgical device with an increase in a boiling percentage of the fluid provided from the surgical device. Alternately or additionally, the fluid flow control mechanism decreases the flow rate of fluid with a decrease in the boiling percentage of the fluid.

In some systems, a fluid flow rate controller and energy source output measurement device are provided, with the fluid flow rate controller providing an output signal to change the flow rate of fluid provided from the surgical device as a result of a change in an input signal that is received from the energy source output measurement device signifying a change in the rate of energy provided from the surgical device.

In some applications, the energy source comprises an electrical generator and the energy comprises alternating current electrical energy. Furthermore, the alternating current electrical energy has a frequency, which is within a frequency band, the frequency band being about 9 kilohertz to 300 gigahertz.

In some systems, the fluid source comprises the fluid within an intravenous bag and the fluid comprises an electrically conductive fluid. The electrically conductive fluid can comprise saline. According to some applications, the flow rate of fluid from the surgical device is about 1 cubic centimeter per minute to 100 cubic centimeters per minute.

In one application, the rate of energy provided from the surgical device is about 1 watt to 400 watts.

In some applications, the energy source comprises a transducer and the energy comprises mechanical energy. In other applications, the energy source comprises a laser and the energy comprises radiant energy.

The surgical device, in some applications, is a monopolar electrosurgical device or a bipolar electrosurgical device.

In select applications, the fluid flow control mechanism comprises a manually activated device for changing, i.e., increasing or decreasing, the flow rate of fluid provided from the surgical device. This manually activated device can be at least one of a roller clamp, a flow rate controller, and a pump. In another select application, the energy control mechanism comprises a manually activated device for increasing or decreasing the rate of energy provided from the surgical device, and can be a selector switch of the energy source.

In other select applications, the fluid flow control mechanism comprises an automatically activated device for increasing or decreasing the fluid flow rate of fluid, and can be a flow rate controller. In another select application, the energy control mechanism comprises an automatically activated device for increasing or decreasing the rate of energy provided from the surgical device, such as an internal component of the energy source.

In some instances, the fluid flow control mechanism changes the flow rate as a result of a change in a rate of energy provided from the surgical device. The flow rate can change from a first non-zero flow rate to a second, non-zero flow rate, or, between any two non-zero flow rates. Similarly, the change in the rate of energy can be from a first non-zero rate of energy to a second non-zero rate of energy, or, between any two non-zero rates of energy.

In some instances, the energy comprises electrical energy and the fluid comprises an electrically conductive fluid. The energy can be electrical energy,

mechanical energy, thermal energy, radiant energy, and ultrasonic energy. The fluid can be electrically conductive fluid or non-electrically conductive fluid.

Certain additional embodiments provide a surgical device for treating tissues. The surgical devices comprises a tip portion comprising a tissue manipulator, the tissue manipulator having cooperating jaws, an energy-providing element operatively associated with the jaws to provide energy to the tissue manipulated by the jaws, a plurality of fluid outlets defined by and along the jaws, the fluid outlets to provide a fluid to the tissue manipulated by the jaws, and at least a portion of the jaws comprising a porous material, the porous material comprising at least one porous material fluid inlet surface and at least one porous material fluid outlet surface, the fluid inlet surface and the fluid outlet surface connected by a plurality of tortuous pathways in the porous material. The porous material can be hydrophilic.

In some applications, at least a portion of the jaws comprise a tissue-manipulating surface; the tissue-manipulating surface interrupted by a recess forming a fluid flow channel comprising a first side wall, a second opposing side wall and a bottom wall, at least a portion of the bottom wall of the flow channel comprising the energy-providing element, the fluid outlets provided through the energy-providing element from a manifold located beneath at least a portion of the energy-providing element, at least a portion of one of the first side wall or second side wall of the fluid flow channel comprising the porous material and at least a portion of the first side wall or second side wall surface comprising the fluid inlet surface and a tissue non-manipulating surface of the jaw comprising the fluid outlet surface.

In a certain embodiment, the surgical device comprises a cutting mechanism configured to retract proximally and extend distally along the jaws.

In some applications, the portion of one of the first side wall or second side wall of the fluid flow channel in the porous material comprises a portion of an outer side wall of the jaw, the portion of the first side wall or second side wall surface comprising the fluid inlet surface comprises an inner surface of an outer side wall and the tissue non-manipulating surface of the jaw comprises an outer surface of the outer side wall.

The porous material can further comprise a second porous material fluid outlet surface, and the second porous material fluid outlet surface can comprise at least a portion of the tissue-manipulating surface.

Another surgical device for treating tissue is also provided by the disclosure. This device comprises a tip portion comprising a tissue manipulator, the tissue manipulator having cooperating jaws, an energy-providing element operatively associated with the jaws to provide energy to the tissue manipulated by the jaws, a

plurality of fluid outlets defined by and along the jaws, the fluid outlets to provide a fluid to the tissue manipulated by the jaws and an output related to the magnitude of a tissue within the jaws.

In some embodiments, the output is configured to provide an estimated tissue treatment time for the tissue or to provide a measurement on a measurement scale. This measurement could be unitless, or the measurement could comprise a tissue dimension (tissue length, tissue width or tissue thickness), or tissue area, or tissue volume. The measurement scale could be located on the surgical device (e.g. jaw, handle), and may comprise a scale of a dial gauge.

In some applications, a surgical device for treating tissue is provided, the device comprising a tip portion comprising a tissue manipulator, the tissue manipulator having cooperating jaws, an energy-providing element operatively associated with the jaws to provide energy to the tissue manipulated by the jaws, a plurality of fluid outlets defined along the jaws, the fluid outlets to provide a fluid to the tissue manipulated by the jaws and a fluid application mechanism which directs application of the fluid only to a portion of the jaws occupied by tissue.

In a further application disclosed, the fluid application mechanism can comprise a plurality of fluid valves which open the fluid outlets as a result of tissue contacting the valves or a gutter which retracts distally along the jaw as a result of tissue contacting a distal end of the gutter and directs fluid application from the distal end of the gutter to tissue.

According to certain techniques of this disclosure, a surgical method for treating tissue is provided. The surgical method comprises providing a surgical device comprising a tip portion, the tip portion comprising a tissue manipulator, the tissue manipulator having cooperating jaws, providing an energy-providing element operatively associated with the jaws to provide energy to the tissue manipulated by the jaws, providing a plurality of fluid outlets defined by and along the jaws, the fluid outlets to provide a fluid to the tissue manipulated by the jaws and providing an output related to the magnitude of a tissue within the jaws.

According to other techniques, a surgical method for treating tissue is provided, the method comprising providing a surgical device comprising a tip portion, the tip portion comprising a tissue manipulator, the tissue manipulator having cooperating jaws, providing an energy-providing element operatively associated with the jaws to provide energy to the tissue manipulated by the jaws, providing a plurality of fluid outlets defined along the jaws, the fluid outlets to provide a fluid to the tissue manipulated by the jaws and providing a fluid application mechanism which directs application of the fluid only to a portion of the jaws occupied by tissue.

Still further techniques provide a surgical method for treating tissue, the method comprising providing energy from energy source, providing a fluid from a fluid source, providing a surgical device which provides the energy and the fluid to the tissue, and changing a flow rate of fluid provided from the surgical device between at least two non-zero flow rates with a change in a rate of energy provided from the surgical device, which changes between at least two non-zero energy rates.

The change in the flow rate of fluid can be performed manually or automatically, and the change in the rate of energy can performed manually or automatically. The change in the flow rate of fluid can be performed independently of the change in the rate of energy provided from the surgical device. Alternately, the change in the flow rate of fluid can be performed dependently on the change in the rate of energy provided from the surgical device.

A further surgical method for treating tissue is provided, the method comprising providing energy from an energy source, providing a fluid from a fluid source, providing a surgical device which provides the energy and the fluid to the tissue, heating the tissue with the energy and controlling the heating of the tissue by vaporizing at least a portion of the fluid.

Another surgical method for treating tissue is provided, the method comprising providing energy from an energy source, providing a fluid from a fluid source, providing a surgical device which provides the energy and the fluid to the tissue, heating and vaporizing at least a portion of the fluid with the energy and changing a flow rate of the fluid to change a boiling percentage of the fluid.

Increasing or decreasing the flow rate of fluid provided from the surgical device preferably respectively increases or decreases the boiling percentage of the fluid.

A surgical method of treating tissue is provided which comprises providing energy from an energy source, providing a fluid from a fluid source, providing a surgical device which provides the energy and the fluid to the tissue, heating the tissue and the fluid with the energy, and dissipating heat from the fluid by vaporizing at least a portion of the fluid.

And further, a surgical method of treating tissue is provided that comprises providing energy from energy source, providing a fluid from a fluid source, the fluid having a boiling temperature, providing a surgical device which provides the energy and the fluid to the tissue, heating the tissue and the fluid with the energy and maintaining the temperature of the tissue at or below the boiling temperature of the fluid by dissipating heat from the fluid by vaporizing at least a portion of the fluid.

Another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency

power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue; forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and using the fluid coupling as an indicator of tissue temperature. In various embodiments, the step of using the fluid coupling as an indicator of tissue temperature may further comprise at least one of using boiling of the fluid coupling as an indicator of tissue temperature, using an amount of boiling of the fluid coupling as an indicator of tissue temperature, and using an onset of boiling of the fluid coupling as an indicator of tissue temperature.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue; forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and using the fluid coupling to cool the tissue.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue, forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and dissipating heat from the tissue by transferring heat to the fluid coupling.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue, forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and dissipating heat from at least one of the tissue and the fluid coupling by a boiling of at least a portion of the fluid coupling.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue, forming a fluid coupling

comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and adjusting at least one of the radio frequency power level and the conductive fluid flow rate based on a boiling of the fluid coupling. In various embodiments, the step of adjusting at least one of the radio frequency power level and the conductive fluid flow rate based on a boiling of the fluid coupling may comprise one of initiating, increasing, decreasing and eliminating boiling of the fluid coupling.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue, forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and limiting the temperature of the tissue at the tissue surface to about a boiling temperature of the fluid coupling.

Yet another surgical method for treating tissue is provided, the method comprising providing tissue having a tissue surface, providing radio frequency power at a power level, providing an electrically conductive fluid at a fluid flow rate, providing an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue, forming a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device, and protecting the tissue from desiccation with the fluid coupling. In various embodiments, the step of protecting the tissue from desiccation with the fluid coupling may further comprise protecting the tissue from desiccation with the fluid coupling by a boiling of at least a portion of the fluid coupling. Furthermore, in various embodiments, the step of protecting the tissue from desiccation with the fluid coupling by a boiling of at least a portion of the fluid coupling may further comprise protecting the tissue from desiccation with the fluid coupling by a boiling of at least a portion of the fluid coupling at a temperature which protects the tissue from desiccation.

Yet another surgical method for treating tissue which may be used with other methods disclosed herein is provided, the method comprising providing the electrically conductive fluid to the tissue at the tissue surface, and providing the radio frequency power to the tissue at the tissue surface and below the tissue surface into the tissue through the fluid coupling.

Brief Description Of The Drawings

FIG. 1 is a block diagram showing one embodiment of the overall control system of the invention, and an electrosurgical device;

FIG. 2 is a schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when heat conduction to adjacent tissue is considered;

FIG. 3 is schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when heat conduction to adjacent tissue is neglected;

FIG. 4 is a schematic graph that describes the relationship between RF power to tissue (P), flow rate of saline (Q), and tissue temperature (T) when the heat required to warm the tissue to the peak temperature (T) **68** is considered;

FIG. 5 is a graph showing the relationship of percentage saline boiling and saline flow rate (cc/min) for an exemplary RF generator output of 75 watts;

FIG. 6 is a schematic graph that describes the relationship of load impedance (Z, in ohms) and generator output power (P, in watts), for an exemplary generator output of 75 watts in a bipolar mode;

FIG. 7 is a schematic graph that describes the relationship of time (t, in seconds) and tissue impedance (Z, in ohms) after RF activation;

FIG. 8 is a schematic side view of one embodiment of a bipolar electrosurgical device;

FIG. 9 is schematic section side view of one embodiment of a bipolar electrosurgical device;

FIG. 10 is a schematic close-up section side view of the tip of the device shown in FIG. 8 and taken along line 10-10 of FIG. 12;

FIG. 11 is a schematic top view of the bipolar electrosurgical device shown in FIG. 8;

FIG. 12 is a schematic close-up section top view of the tip of the device shown in FIG. 11 with jaw **18a** removed;

FIG. 13 is a schematic close-up section side view of the electrodes of the device shown in FIG. 11 showing saline shunting without boiling of the saline;

FIG. 14 is a diagram that describes the equivalent electrical circuit for tissue in parallel with a single saline shunt;

FIG. 15 is a graph that describes the relationship of ratio of saline to tissue resistance (R_s/R_t) and percent power shunted into saline;

FIG. 16 is a schematic close-up side section view of the electrodes of the device shown in FIG. 11 showing a large percentage of the saline boiling at the tissue treatment site;

FIG. 17 is a schematic close-up side section view of electrodes of the device shown in FIG. 11 showing two gutters slid out to direct saline flow distally toward tissue;

FIG. 18 is a schematic close-up cross-section view along line A-A of FIG. 17, showing the two gutters positioned to collect and direct saline flow distally;

FIG 19 is a schematic close-up cross-section view of one embodiment of the jaws of the device shown in FIG. 11, wherein the jaws include a tissue-activated valve in a seated position;

FIG 20 is a schematic close-up cross-section view of one embodiment of the jaws of the device shown in FIG. 11, wherein the jaws include a tissue-activated valve in an unseated position;

FIG. 21 is a schematic close-up side section view of one embodiment of the jaws of the device shown in FIG. 11, wherein the jaws include tissue-activated valves to direct flow distally;

FIG. 22 is a schematic close-up side section view showing the gutters of FIG. 17 being used in conjunction with right triangles to determine the cross-sectional area of the tissue;

FIG. 23 is a close-up front view of a dial gauge which may be used with the electrosurgical device;

FIG. 24 is a side view of a rack and pinion which may be used to connect the dial gauge of FIG. 23 to the electrosurgical device;

FIG. 25 is a schematic close-up cross-section view along line A-A of FIG. 17, showing and alternative embodiment of the jaws;

FIG. 26 is a schematic close-up cross-section view along line A-A of FIG. 17, showing and alternative embodiment of the jaws;

FIG. 27 is schematic perspective view of a tip of another embodiment showing the jaws in an open position;

FIG. 28 is a schematic side view of the tip portion of FIG. 27 with the jaws in a closed position;

FIG. 29 is a section view taken along line 29-29 of FIG. 28;

FIG. 30 is a section view taken along line 30-30 of FIG. 28;

FIG. 31 a schematic front perspective view of jaw **18b** of FIG. 27 with jaw **18a** removed and electrode **25b** removed; and

FIG. 32 a schematic rear perspective view of jaw **18b** of FIG. 27 with jaw **18a** removed and electrode **25b** removed.

Detailed Description

Throughout the present description, like reference numerals and letters indicate corresponding structure throughout the several views, and such corresponding structure need not be separately discussed. For elements similar to the various exemplary embodiments of the invention, an attempt has been made to hold each reference character within a particular numerical series constant. In other words, for example, an element referenced at 10 in one exemplary embodiment is correspondingly referenced at 110, 210, and so forth in subsequent exemplary embodiments. Thus, where an exemplary embodiment description uses a reference numeral to refer to an element, the reference numeral generally applies equally, as distinguished by series, to the other exemplary embodiments where the element is common. Furthermore, any particular feature(s) of a particular exemplary embodiment may be equally applied to any other exemplary embodiment(s) of this specification as suitable. In other words, features between the various exemplary embodiments described herein are interchangeable, and not exclusive.

The invention provides systems, devices and methods that preferably improve control of tissue temperature at a treatment site during a medical procedure. The invention is particularly useful during surgical procedures upon tissues of the body, where tissue is often cut and coagulated. The invention preferably involves the use of electrosurgical procedures, which preferably utilize RF power and a fluid to treat tissue. Preferably, a desired tissue temperature range is achieved through adjusting parameters, such as fluid flow rate, that affect the temperature at the tissue/electrode interface. In one embodiment, a device may achieve a desired tissue temperature utilizing a desired percentage boiling of the fluid at the tissue/electrode interface. In another embodiment, the invention provides a control device, the device comprising a flow rate controller that receives a signal indicating power applied to the system, and adjusts the flow rate of conductive fluid from a fluid source to an electrosurgical device. The invention also contemplates a control system comprising a flow rate controller, a measurement device that measures power applied to the system, and a pump that provides fluid at a selected flow rate.

The invention will be discussed generally with reference to FIG. 1. FIG. 1 shows a block diagram of one exemplary embodiment of a system of the invention. Preferably, as shown in FIG. 1, a fluid is provided from a fluid source 1, through a fluid line 2, to a pump 3, which has an outlet fluid line 4 that is connected to an electrosurgical device 5. In one embodiment, the fluid may comprise a saline solution. More preferably, the saline may comprise sterile, and even more preferably, normal saline. Although a portion of the description herein will specifically describe the use of saline as the fluid, other electrically conductive

fluids, as well as non-conductive fluids, can be used in accordance with the invention.

For example, in addition to a conductive fluid comprising physiologic saline (also known as "normal" saline, isotonic saline or 0.9% sodium chloride (NaCl) solution), the conductive fluid may comprise hypertonic saline solution, hypotonic saline solution, Ringers solution (a physiologic solution of distilled water containing specified amounts of sodium chloride, calcium chloride, and potassium chloride), lactated Ringer's solution (a crystalloid electrolyte sterile solution of distilled water containing specified amounts of calcium chloride, potassium chloride, sodium chloride, and sodium lactate), Locke-Ringer's solution (a buffered isotonic solution of distilled water containing specified amounts of sodium chloride, potassium chloride, calcium chloride, sodium bicarbonate, magnesium chloride, and dextrose), or any other electrolyte solution. In other words, a solution that conducts electricity via an electrolyte, a substance (salt, acid or base) that dissociates into electrically charged ions when dissolved in a solvent, such as water, resulting solution comprising an ionic conductor.

As will become more apparent with further reading of this specification, the fluid may also comprise an electrically non-conductive fluid. In certain embodiments, the use of a non-conductive fluid may be less preferred to that of a conductive fluid as the non-conductive fluid does not conduct electricity. However, the use of a non-conductive fluid still provides certain advantages over the use of a dry electrode including, for example, reduced occurrence of tissue sticking to the electrode, cooling of tissue and/or the electrode, and removal of any coagula, if existent, from the electrodes and/or the tissue treatment site. Furthermore, in other embodiments, the use of a non-conductive fluid may be preferred to the use of a conductive fluid to reduce electrical shunting through the fluid as described in greater detail herein. Therefore, it is also within the scope of the invention to include the use of a non-conductive fluid, such as, for example, dionized water. Other non-conductive fluids include 5% w/v dextrose injection USP and 10% w/v dextrose injection USP (i.e. sterile solutions of 5g and 10g dextrose hydrous in 100ml water, respectively); 1.5% w/v glycine irrigation USP (i.e. sterile solution of 1.5 g glycine in 100ml water); 5% w/v, 10% w/v, 15% w/v and 20% w/v mannitol injection USP (i.e. sterile solution of 5g, 10g, 15g and 20g mannitol in 100ml water, respectively); 3% sorbitol irrigation USP (i.e. sterile solution of 3g sorbitol in 100 ml water); 0.54% sorbitol/2.75% mannitol irrigation USP (i.e. sterile solution of 0.54g sorbitol and 2.75g mannitol in 100 ml water); and sterile water for irrigation USP.

Energy to heat tissue is provided from an energy source, such as an electrical generator **6** which preferably provides RF alternating current energy via a cable **7** to energy source output measurement device, such as a power measurement device **8** that measures the RF alternating current electrical power. In this exemplary embodiment, preferably the power measurement device **8** does not turn the power off or on, or alter the power in any way. A power switch **15** connected to the generator **6** is preferably provided by the generator manufacturer and is used to turn the generator **6** on and off. The power switch **15** can comprise any switch to turn the power on and off, and is commonly provided in the form of a footswitch or other easily operated switch, such as a switch **15a** mounted on the electrosurgical device **5**. The power switch may also function as a manually activated device for increasing or decreasing the rate of energy provided from the surgical device **5**. Alternatively, internal circuitry and other components of the generator 6 may be used for automatically increasing or decreasing the rate of energy provided from the surgical device **5**. A cable **9** preferably carries RF energy from the power measurement device **8** to the electrosurgical device **5**. Power, or any other energy source output, is preferably measured before it reaches the electrosurgical device **5**.

For the situation where capacitation and induction effects are negligibly small, from Ohm's law, power **P**, or the rate of energy delivery (e.g. joules/sec), may be expressed by the product of current times voltage (i.e. I x V), the current squared times resistance (i.e. I^2 x R), or the voltage squared divided by the resistance (i.e. V^2/R); where the current **I** may be measured in amperes, the voltage **V** may be measured in volts, the electrical resistance **R** may be measured in ohms, and the power **P** may be measured in watts (joules/sec). Given that power **P** is a function of current **I**, voltage **V**, and resistance **R** as indicated above, it should be understood, that a change in power **P** is reflective of a change in at least one of the input variables. Thus, one may alternatively measure changes in such input variables themselves, rather than power **P** directly, with such changes in the input variables mathematically corresponding to a changes in power **P** as indicated above.

As to the frequency of the RF electrical energy, it is preferably provided within a frequency band (i.e. a continuous range of frequencies extending between two limiting frequencies) in the range between and including about 9 kHz (kilohertz) to 300 GHz (gigahertz). More preferably, the RF energy is provided within a frequency band in the range between and including about 50 kHz (kilohertz) to 50 MHz (megahertz). Even more preferably, the RF energy is provided within a frequency band in the range between and including about 200 kHz (kilohertz) to 2 MHz (megahertz). Most preferably, RF energy is provided within a frequency band in the range between and including about 400 kHz (kilohertz) to 600 kHz

(kilohertz). Further, it should also be understood that, for any frequency band identified above, the range of frequencies may be further narrowed in increments of 1 (one) hertz anywhere between the lower and upper limiting frequencies.

While RF electrical energy is preferred, it should be understood that the electrical energy (i.e., energy made available by the flow of electric charge, typically through a conductor or by self-propagating waves) may comprise any frequency of the electromagnetic spectrum (i.e. the entire range of radiation extending in frequency from 10^{23} hertz to 0 hertz) and including, but not limited to, gamma rays, x-rays, ultraviolet radiation, visible light, infrared radiation, microwaves, and any combinations thereof.

With respect to the use of electrical energy, heating of the tissue is preferably performed by means of resistance heating. In other words, increasing the temperature of the tissue as a result of electric current flow through the tissue, with the electrical energy being absorbed from the voltage and transformed into thermal energy (i.e. heat) via accelerated movement of ions as a function of the tissue's electrical resistance.

Heating with electrical energy may also be performed by means of dielectric heating (capacitation). In other words, increasing the temperature of the tissue through the dissipation of electrical energy as a result of internal dielectric loss when the tissue is placed in a varying electric field, such as a high-frequency (e.g. microwave), alternating electromagnetic field. Dielectric loss is the electrical energy lost as heat in the polarization process in the presence of the applied electric field. In the case of an alternating current field, the energy is absorbed from the alternating current voltage and converted to heat during the polarization of the molecules.

However, it should be understood that energy provided to heat the tissue may comprise surgical devices other than electrosurgical devices, energy sources other than generators, energy forms other than electrical energy and mechanisms other than resistance heating. For example, providing thermal energy to the tissue from energy source with a difference (e.g. higher) in temperature. Such may be provided, for example, to the tissue from a heated device, which heats tissue through direct contact with the energy source (conduction), heats through contact with a flowing fluid (convection), or from a remote heat source (radiation).

Also, for example, providing energy to the tissue may be provided via mechanical energy which is transformed into thermal energy via accelerated movement of the molecules, such as by mechanical vibration provided, for example, by energy source such as a transducer containing a piezoelectric substance (e.g., a

quartz-crystal oscillator) that converts high-frequency electric current into vibrating ultrasonic waves which may be used by, for example, an ultrasonic surgical device.

Also, for example, providing energy to the tissue may be provided via radiant energy (i.e. energy which is transmitted by radiation/waves) which is transformed into thermal energy via absorption of the radiant energy by the tissue. Preferably the radiation/waves comprise electromagnetic radiation/waves which include, but is not limited to, radio waves, microwaves, infrared radiation, visible light radiation, ultraviolet radiation, x-rays and gamma rays. More preferably, such radiant energy comprises energy with a frequency of 3×10^{11} hertz to 3×10^{16} hertz (i.e. the infrared, visible, and ultraviolet frequency bands of the electromagnetic spectrum). Also preferably the electromagnetic waves are coherent and the electromagnetic radiation is emitted from energy source such as a laser device. A flow rate controller **11** preferably includes a selection switch **12** that can be set to achieve desired levels of percentage fluid boiling (for example, 100%, 98%, 80% boiling). Preferably, the flow rate controller **11** receives an input signal **10** from the power measurement device **8** and calculates an appropriate mathematically predetermined fluid flow rate based on percentage boiling indicated by the selection switch **12**. In a preferred embodiment, a fluid switch **13** is provided so that the fluid system can be primed (air eliminated) before turning the generator **6** on. The output signal **16** of the flow rate controller **11** is preferably sent to the pump **3** motor to regulate the flow rate of fluid, and thereby provide an appropriate fluid flow rate which corresponds to the amount of power being delivered.

In one exemplary embodiment, the invention comprises a flow rate controller that is configured and arranged to be connected to a source of RF power, and a source of fluid, for example, a source of conductive fluid. The device of the invention receives information about the level of RF power applied to an electrosurgical device, and adjusts the flow rate of the fluid to the electrosurgical device, thereby controlling temperature at the tissue treatment site.

In another exemplary embodiment, elements of the system are physically included together in one electronic enclosure. One such embodiment is shown by enclosure within the outline box **14** of FIG 1. In the illustrated embodiment, the pump **3**, flow rate controller **11**, and power measurement device **8** are enclosed within an enclosure, and these elements are connected through electrical connections to allow signal **10** to pass from the power measurement device **8** to the flow rate controller **11**, and signal **16** to pass from the flow rate controller **11** to the pump **3**. Other elements of a system can also be included within one enclosure, depending upon such factors as the desired application of the system, and the requirements of the user.

The pump 3 can be any suitable pump used in surgical procedures to provide saline or other fluid at a desired flow rate. Preferably, the pump 3 comprises a peristaltic pump. With a rotary peristaltic pump, typically a fluid is conveyed within the confines of a flexible tube by waves of contraction placed externally on the tube which are produced mechanically, typically by rotating rollers which squeeze the flexible tubing against a support intermittently. Alternatively, with a linear peristaltic pump, typically a fluid is conveyed within the confines of a flexible tube by waves of contraction placed externally on the tube which are produced mechanically, typically by a series of compression fingers or pads which squeeze the flexible tubing against a support sequentially. Peristaltic pumps are generally preferred for use as the electro-mechanical force mechanism (e.g. rollers driven by electric motor) does not make contact the fluid, thus reducing the likelihood of inadvertent contamination.

Alternatively, pump 3 can be a "syringe pump", with a built-in fluid supply. With such a pump, typically a filled syringe is located on an electro-mechanical force mechanism (e.g. ram driven by electric motor) which acts on the plunger of the syringe to force delivery of the fluid contained therein. Alternatively, the syringe pump may comprise a double-acting syringe pump with two syringes such that they can draw saline from a reservoir, either simultaneously or intermittently. With a double acting syringe pump, the pumping mechanism is generally capable of both infusion and withdrawal. Typically, while fluid is being expelled from one syringe, the other syringe is receiving fluid therein from a separate reservoir. In this manner, the delivery of fluid remains continuous and uninterrupted as the syringes function in series. Alternatively, it should be understood that a multiple syringe pump with two syringes, or any number of syringes, may be used in accordance with the invention.

Furthermore, fluid, such as conductive fluid, can also be provided from an intravenous (IV) bag full that flows under the influence (i.e. force) of gravity. In such a manner, the fluid may flow directly to the electrosurgical device 5, or first to the pump 3 located there between. Alternatively, fluid from a fluid source such as an IV bag can be provided through an IV flow controller that may provide a desired flow rate by adjusting the cross sectional area of a flow orifice (e.g. lumen of the connective tubing with the electrosurgical device) while sensing the flow rate with a sensor such as an optical drop counter. Furthermore, fluid from a fluid source such as an IV bag an be provided through a manually or automatically activated device such as a flow controller, such as a roller clamp, which also adjusts the cross sectional area of a flow orifice and may be adjusted manually by, for example, the

user of the device in response to their visual observation (e.g. fluid boiling) at the tissue treatment site or a pump.

Similar pumps can be used in connection with the invention, and the illustrated embodiments are exemplary only. The precise configuration of the pump 3 is not critical to the invention. For example, pump 3 may include other types of infusion and withdrawal pumps. Furthermore, pump 3 may comprise pumps which may be categorized as piston pumps, rotary vane pumps (e.g. blower, axial impeller, centrifugal impeller), cartridge pumps and diaphragm pumps. In some embodiments, the pump can be substituted with any type of flow controller, such as a manual roller clamp used in conjunction with an IV bag, or combined with the flow controller to allow the user to control the flow rate of conductive fluid to the device. Alternatively, a valve configuration can be substituted for pump 3.

Furthermore, similar configurations of the system can be used in connection with the invention, and the illustrated embodiments are exemplary only. For example, the fluid source 1 pump 3, generator 6, power measurement device 8 or flow rate controller 11, or any other components of the system not expressly recited above, may comprise a portion of the electrosurgical device 5. For example, in one exemplary embodiment the fluid source may comprise a compartment of the electrosurgical device 5 which contains fluid, as indicated at reference character 1a. In another exemplary embodiment, the compartment may be detachably connected to the electrosurgical device 5, such as a canister which may be attached via threaded engagement with the device 5. In yet another exemplary embodiment, the compartment may be configured to hold a pre-filled cartridge of fluid, rather than the fluid directly.

Also for example, with regards to the generator, energy source, such as a direct current (DC) battery used in conjunction with inverter circuitry and a transformer to produce alternating current at a particular frequency, may comprise a portion of the electrosurgical device 5, as indicated at reference character 6a. In one embodiment the battery element of the energy source may comprise a rechargeable battery. In yet another exemplary embodiment, the battery element may be detachably connected to the electrosurgical device 5, such as for recharging. In yet other exemplary embodiments, either the fluid or the energy source may be located on (e.g. within) the proximal (to the user of the device 5a) handle 20 (see FIG. 7) of the electrosurgical device 5, or the shaft 17 of the electrosurgical device 5. Handle 20 is preferably made of a sterilizable, rigid, and non-conductive material, such as a polymer (e.g. polycarbonate). The components of the system will now be described in further detail. From the specification, it should be clear that any use of the terms

"distal" and "proximal" are made in reference from the user of the device, and not the patient.

The flow rate controller **11** controls the rate of flow from the fluid source **1**. Preferably, the rate of fluid flow from the fluid source **1** is based upon the amount of RF power provided from the generator **6** to the electrosurgical device **5**. In other words, as shown in FIG. **2**, preferably there is a relationship between the rate of fluid flow and the RF power. More precisely, as shown in FIG. **2**, the relationship between the rate of fluid flow and RF power may be expressed as a direct, linear relationship. The flow rate of fluid, such as saline, interacts with the RF power and various modes of heat transfer away from the target tissue and electrodes, as described herein.

Throughout this disclosure, when the terms "boiling point of saline", "vaporization point of saline", and variations thereof are used, what is intended is the boiling point of the water in the saline solution.

FIG. **2** shows a schematic graph that describes the relationship between the flow rate of saline, RF power to tissue, and regimes of boiling as detailed below. Based on a simple one-dimensional lumped parameter model of the heat transfer, the peak tissue temperature can be estimated, and once tissue temperature is estimated, it follows directly whether it is hot enough to boil saline.

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v \qquad (1)$$

where P = the total RF electrical power that is converted into heat.

Conduction. The first term [$\Delta T/R$] in equation (1) is heat conducted to adjacent tissue, represented as **70** in FIG. **2**, where:

ΔT = ($T - T_\infty$) the difference in temperature between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C). Normal temperature of the body tissue is generally 37 °C; and

R = Thermal resistance of surrounding tissue, the ratio of the temperature difference to the heat flow (°C/watt).

This thermal resistance can be estimated from published data gathered in experiments on human tissue (Phipps, J.H., "Thermometry studies with bipolar diathermy during hysterectomy," *Gynaecological Endoscopy*, 3:5-7 (1994)). As described by Phipps, Kleppinger bipolar forceps were used with an RF power of 50

watts, and the peak tissue temperature reached 320 °C. For example, using the energy balance of equation (1), and assuming all the RF heat put into tissue is conducted away, then R can be estimated:

$$R = \Delta T/P = (320\text{-}37)/50 = 5.7 \approx 6\ ^\circ C/watt$$

However, it is undesirable to allow the tissue temperature to reach 320 °C, since tissue will become desiccated. At a temperature of 320 °C, the fluid contained in the tissue is typically boiled away, resulting in the undesirable tissue effects described herein. Rather, it is preferred to keep the peak tissue temperature at no more than about 100 °C to inhibit desiccation of the tissue. Assuming that saline boils at about 100 °C, the first term in equation (1) ($\Delta T/R$) is equal to $(100 - 37)/6 =$ 10.5 watts. Thus, based on this example, the maximum amount of heat conducted to adjacent tissue without any significant risk of tissue desiccation is 10.5 watts.

Referring to FIG. 2, RF power to tissue is represented on the X-axis as **P** (watts) and flow rate of saline (cc/min) is represented on the Y-axis as **Q**. When the flow rate of saline equals zero ($Q = 0$), there is an "offset" RF power that shifts the origin of the sloped lines **76**, **78**, and **80** to the right. This offset is the heat conducted to adjacent tissue. For example, using the calculation above for bipolar forceps, this offset RF power is about 10.5 watts. If the power is increased above this level with no saline flow, the peak tissue temperature can rise well above 100 °C, resulting in tissue desiccation from the boiling off of water in the cells of the tissue.

Convection. The second term $[\rho c_\rho Q_l \Delta T]$ in equation (1) is heat used to warm up the flow of saline without boiling the saline, represented as **72** in FIG. 2, where:

ρ = Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm^3);

c_ρ = Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);

Q_l = Flow rate of the saline that is heated (cm^3/sec); and

ΔT = Temperature rise of the saline. Assuming that the saline is heated to body temperature before it gets to the electrode, and that the peak saline temperature is similar to the peak tissue temperature, this is the same ΔT as for the conduction calculation above.

The onset of boiling can be predicted using equation (1) with the last term on the right set to zero (no boiling) ($\rho Q_b h_v = 0$), and solving equation (1) for Q_l leads to:

$$Q_l = [P - \Delta T/R]/\rho c_p \Delta T \qquad (2)$$

This equation defines the line shown in FIG. **2** as the line of onset of boiling **76**.

Boiling. The third term $[\rho Q_b h_v]$ in equation (1) relates to heat that goes into converting the water in liquid saline to water vapor, and is represented as **74** in FIG. **2**, where:

Q_b = Flow rate of saline that boils (cm^3/sec); and

h_v = Heat of vaporization of saline (approximately 2,000 watt-sec/gm).

A flow rate of only 1 cc/min will absorb a significant amount of heat if it is completely boiled, or about $\rho Q_b h_v = (1)\ (1/60)\ (2{,}000) = 33.3$ watts. The heat needed to warm this flow rate from body temperature to 100 °C is much less, or $\rho c_p Q_l \Delta T = (1)\ (4.1)\ (1/60)\ (100 - 37) = 4.3$ watts. In other words, the most significant factor contributing to heat transfer from a wet electrode device can be fractional boiling. The present invention recognizes this fact and exploits it.

Fractional boiling can be described by equation (3) below:

$$Q_l = \frac{\{P - \Delta T/R\}}{\{\rho c_p \Delta T + \rho h_v Q_b/Q_l\}} \qquad (3)$$

If the ratio of Q_b/Q_l is 0.50 this is the 50% boiling line **78** shown in FIG. **2**. If the ratio is 1.0 this is the 100% boiling line **80** shown in FIG. **2**.

As indicated previously in the specification, using a fluid to couple energy to tissue inhibits such undesirable effects as sticking, desiccation, smoke production and char formation, and that one key factor is inhibiting tissue desiccation, which occur if the tissue temperature exceeds 100 °C and all the intracellular water boils away, leaving the tissue extremely dry and much less electrically conductive.

As shown in FIG. **2**, one control strategy or mechanism which can be employed for the electrosurgical device **5** is to adjust the power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** is equal to or less than the power **P** required to boil 100% of the fluid and does not exceed the power **P** required to boil 100% of the fluid. In other words, this control strategy targets using the electrosurgical device **5** in the regions of FIG. **2** identified as $T < 100$ °C and $T = 100$ °C, and includes the 100% boiling line **80**. Stated another way, this control strategy targets not using the electrosurgical device **5** only in the region of FIG. **2** identified as $T >> 100$ °C.

Another control strategy that can be used for the electrosurgical device **5** is to operate the device **5** in the region T < 100 °C, but at high enough temperature to shrink tissue containing Type I collagen (e.g., walls of blood vessels, bronchi, bile ducts, etc.), which shrinks when exposed to about 85 °C for an exposure time of 0.01 seconds, or when exposed to about 65 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue shrinkage is about 75 °C with an exposure time of about 1 second. As discussed herein, a determination of the high end of the scale (i.e., when the fluid reaches 100 °C) can be made by the phase change in the fluid from liquid to vapor. However, a determination at the low end of the scale (e.g., when the fluid reaches, for example, 75 °C for 1 second) requires a different mechanism as the temperature of the fluid is below the boiling temperature and no such phase change is apparent. In order to determine when the fluid reaches a temperature that will facilitate tissue shrinkage, for example 75 °C, a thermochromic material, such as a thermochromic dye (e.g., leuco dye), may be added to the fluid. The dye can be formulated to provide a first predetermined color to the fluid at temperatures below a threshold temperature, such as 75 °C, then, upon heating above 75 °C, the dye provides a second color, such as clear, thus turning the fluid clear (i.e. no color or reduction in color). This color change may be gradual, incremental, or instant. Thus, a change in the color of the fluid, from a first color to a second color (or lack thereof) provides a visual indication to the user of the electrosurgical device **5** as to when a threshold fluid temperature below boiling has been achieved. Thermochromic dyes are available, for example, from Color Change Corporation, 1740 Cortland Court, Unit A, Addison, IL 60101.

It is also noted that the above mechanism (i.e., a change in the color of the fluid due to a dye) may also be used to detect when the fluid reaches a temperature which will facilitate tissue necrosis; this generally varies from about 60 °C for an exposure time of 0.01 seconds and decreasing to about 45 °C for an exposure time of 15 minutes. An exemplary target temperature/time for tissue necrosis is about 55 °C for an exposure time of about 1 second.

In order to reduce coagulation time, use of the electrosurgical device **5** in the region T = 100 °C of FIG. **2** is preferable to use of the electrosurgical device **5** in the region T < 100 °C. Consequently, as shown in FIG. **2**, another control strategy which may be employed for the electrosurgical device **5** is to adjust the power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** is equal to or more than the power **P** required to initiate boiling of the fluid, but still less than the power **P** required to boil 100% of the fluid. In other words, this control strategy targets using the electrosurgical device **5** in the region of FIG. **2** identified as T = 100 °C, and includes the lines of the onset of boiling **76** and 100% boiling line **80**.

Stated another way, this control strategy targets use using the electrosurgical device **5** on or between the lines of the onset of boiling **76** and 100% boiling line **80**, and not using the electrosurgical device **5** in the regions of FIG. **2** identified as $T < 100$ °C and $T >> 100$ °C.

For consistent tissue effect, it is desirable to control the saline flow rate so that it is always on a "line of constant % boiling" as, for example, the line of the onset of boiling **76** or the 100% boiling line **80** or any line of constant % boiling located in between (e.g. 50% boiling line **78**) as shown in FIG. **2**. Consequently, another control strategy that can be used for the electrosurgical device **5** is to adjust power **P** and flow rate **Q** such that the power **P** used at a corresponding flow rate **Q** targets a line of constant % boiling.

It should be noted, from the preceding equations, that the slope of any line of constant % boiling is known. For example, for the line of the onset of boiling **76**, the slope of the line is given by $(\rho c_p \Delta T)$, while the slope of the 100% boiling line **80** is given by $1/(\rho c_p \Delta T + \rho h_v)$. As for the 50% boiling line **78**, for example, the slope is given by $1/(\rho c_p \Delta T + \rho h_v 0.5)$.

If, upon application of the electrosurgical device **5** to the tissue, boiling of the fluid is not detected, such indicates that the temperature is less than 100 °C as indicated in the area of FIG. **2**, and the flow rate **Q** must be decreased to initiate boiling. The flow rate **Q** may then decreased until boiling of the fluid is first detected, at which time the line of the onset of boiling **76** is transgressed and the point of transgression on the line **76** is determined. From the determination of a point on the line of the onset of boiling **76** for a particular power **P** and flow rate **Q**, and the known slope of the line **76** as outlined above (i.e. $1/\rho c_p \Delta T$), it is also possible to determine the heat conducted to adjacent tissue **70**.

Conversely, if upon application of the electrosurgical device **5** to the tissue, boiling of the fluid is detected, such indicates that the temperature is approximately equal to 100 °C as indicated in the areas of FIG. **2**, and the flow rate **Q** must be increased to reduce boiling until boiling stops, at which time the line of the onset of boiling **76** is transgressed and the point of transgression on the line **76** determined. As with above, from the determination of a point on the line of the onset of boiling **76** for a particular power **P** and flow rate **Q**, and the known slope of the line **76**, it is also possible to determine the heat conducted to adjacent tissue **70**.

With regards to the detection of boiling of the fluid, such may be physically detected by the user (e.g. visually by the naked eye) of the electrosurgical device **5** in the form of either bubbles or steam evolving from the fluid coupling at the electrode/tissue interface. Alternatively, such a phase change (i.e. from liquid to vapor or vice-versa) may be measured by a sensor (See FIG. **10** at **79**) which

preferably senses either an absolute change (e.g. existence or non-existence of boiling with binary response such as yes or no) or a change in a physical quantity or intensity and converts the change into a useful input signal for an information-gathering system. For example, the phase change associated with the onset of boiling may be detected by a pressure sensor, such as a pressure transducer, located on the electrosurgical device **5**. Alternatively, the phase change associated with the onset of boiling may be detected by a temperature sensor, such as a thermistor or thermocouple, located on the electrosurgical device **5**, such as adjacent to the electrode. Also alternatively, the phase change associated with the onset of boiling may be detected by a change in the electric properties of the fluid itself. For example, a change in the electrical resistance of the fluid may be detected by an ohm meter; a change in the amperage may be measured by an amp meter; as change in the voltage may be detected by a volt meter; and a change in the power may be determined by a power meter.

Yet another control strategy which may be employed for the electrosurgical device **5** is to eliminate the heat conduction term of equation (1) (i.e. $\Delta T/R$). Since the amount of heat conducted away to adjacent tissue can be difficult to precisely predict, as it may vary, for example, by tissue type, it may be preferable, from a control point of view, to assume the worst case situation of zero heat conduction, and provide enough saline so that if necessary, all the RF power could be used to heat up and boil the saline, thus providing that the peak tissue temperature will not go over 100 °C a significant amount. This situation is shown in the schematic graph of FIG. **3**.

Stated another way, if the heat conducted to adjacent tissue **70** is overestimated, the power **P** required to intersect the 100% boiling line **80** will, in turn, be overestimated and the 100% boiling line **80** will be transgressed into the T >> 100 °C region of FIG. **2**, which is undesirable as established above. Thus, assuming the worse case situation of zero heat conduction provides a "safety factor" to avoid transgressing the 100% boiling line **80**. Assuming heat conduction to adjacent tissue **70** to be zero also provides the advantage of eliminating the only term from equation (1) which is tissue dependent, i.e., depends on tissue type. Thus, provided ρ, c_p, ΔT, and h_v are known as indicated above, the equation of the line for any line of constant % boiling is known. Thus, for example, the 98% boiling line, 80% boiling line, etc. can be determined in response to a corresponding input from the selection switch **12**. In order to promote flexibility, it should be understood that the input from the selection switch preferably may comprise any percentage of boiling. Preferably the percentage of boiling may be selected in single percent increments (i.e. 100%, 99%, 98%, etc.).

Upon determination of the line of the onset of boiling **76**, the 100% boiling line **80** or any line of constant % boiling there between, it is generally desirable to control the flow rate **Q** so that it is always on a particular line of constant % boiling for consistent tissue effect. In such a situation, the flow rate controller **11** will adjust the flow rate **Q** of the fluid to reflect changes in power **P** provided by the generator **6**, as discussed in greater detail below. For such a use the flow rate controller may be set in a line of constant boiling mode, upon which the % boiling is then correspondingly selected.

As indicated above, it is desirable to control the saline flow rate **Q** so that it is always on a line of constant % boiling for consistent tissue effect. However, the preferred line of constant % boiling may vary based on the type of electrosurgical device **5**. For example, if shunting through saline is not an issue (as will be described in further detail herein), then it can be preferable to operate close to or directly on, but not over the line of the onset of boiling, such as **76a** in FIG. **3**. This preferably keeps tissue as hot as possible without causing desiccation. Alternatively, if shunting of electrical energy through excess saline is an issue, then it can be preferable to operate along a line of constant boiling, such as line **78a** in FIG. **3**, the 50% line. This simple proportional control will have the flow rate determined by equation (4), where **K** is the proportionality constant:

$$Q_l = K \times P \qquad (4)$$

In essence, when power **P** goes up, the flow rate **Q** will be proportionately increased. Conversely, when power **P** goes down, the flow rate **Q** will be proportionately decreased.

The proportionality constant **K** is primarily dependent on the fraction of saline that boils, as shown in equation (5), which is equation (3) solved for **K** after eliminating **P** using equation (4), and neglecting the conduction term ($\Delta T/R$):

$$K = \frac{1}{\{\rho c_p \Delta T + \rho h_v Q_b / Q_l\}} \qquad (5)$$

Thus, the present invention provides a method of controlling boiling of fluid, such as a conductive fluid, at the tissue/electrode interface. In a preferred embodiment, this provides a method of treating tissue without use of tissue sensors, such as temperature or impedance sensors. Preferably, the invention can control boiling of conductive fluid at the tissue/electrode interface and thereby control tissue temperature without the use of feedback loops.

In describing the control strategy in relation for the electrosurgical devices of the present invention described thus far, focus has been drawn to a steady state condition. However, the heat required to warm the tissue to the peak temperature (T) may be incorporated into equation (1) as follows:

$$P = \Delta T/R + \rho c_p Q_l \Delta T + \rho Q_b h_v + \rho c_p V \Delta T/\Delta t \qquad (6)$$

where $\rho c_p V \Delta T/\Delta t$ represents the heat required to warm the tissue to the peak temperature (T) **68** and where :

$\rho =$ Density of the saline fluid that gets hot but does not boil (approximately 1.0 gm/cm^3);

$c_p =$ Specific heat of the saline (approximately 4.1 watt-sec/gm-°C);

$V =$ Volume of treated tissue

$\Delta T =$ $(T - T_\infty)$ the difference in temperature between the peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C). Normal temperature of the body tissue is generally 37 °C; and

$\Delta t =$ $(t - t_\infty)$ the difference in time to achieve peak tissue temperature (T) and the normal temperature (T_∞) of the body tissue (°C).

The inclusion of the heat required to warm the tissue to the peak temperature (T) in the control strategy is graphically represented at **68** in FIG. **4**.

With respect to the control strategy, the effects of the heat required to warm the tissue to the peak temperature (T) **68** should be taken into account before flow rate **Q** adjustment being undertaken to detect the location of the line of onset of boiling **76**. In other words, the flow rate **Q** should not be decreased in response to a lack of boiling before at least a quasi-steady state has been achieved as the location of the line of onset of boiling **76** will continue to move during the transitory period. Otherwise, if the flow rate **Q** is decreased during the transitory period, it may be possible to decrease the flow **Q** to a point past the line of onset of boiling **76** and continue past the 100% boiling line **80** which is undesirable. In other words, as temperature (T) is approached the heat 68 diminishes towards zero such that the lines of constant boiling shift to the left towards the Y-axis.

FIG. **5** shows an exemplary graph of flow rate **Q** versus % boiling for a situation where the RF power **P** is 75 watts. The percent boiling is represented on the X-axis, and the saline flow rate **Q** (cc/min) is represented on the Y-axis. According to this example, at 100 % boiling the most desirable predetermined saline flow rate **Q** is 2 cc/min. Also according to this example, flow rate **Q** versus %

boiling at the remaining points of the graft illustrates a non-linear relationship as follows:

Table 1 – % Boiling and Flow Rate **Q** (cc/min) at RF Power **P** of 75 watts

0%	17.4
10%	9.8
20%	6.8
30%	5.2
40%	4.3
50%	3.6
60%	3.1
70%	2.7
80%	2.4
90%	2.2
100%	2.0

Typical RF generators used in the field have a power selector switch to 300 watts of power, and on occasion some have been found to be selectable up to 400 watts of power. In conformance with the above methodology, at 0% boiling with a corresponding power of 300 watts, the calculated flow rate **Q** is 69.7 cc/min and with a corresponding power of 400 watts the calculated flow rate **Q** is 92.9 cc/min. Thus, when used with typical RF generators in the field, a fluid flow rate **Q** of about 100 cc/min or less with the present invention is expected to suffice for the vast majority of applications.

As discussed herein, RF energy delivery to tissue can be unpredictable and vary with time, even though the generator has been "set" to a fixed wattage. The schematic graph of FIG. **6** shows the general trends of the output curve of a typical general-purpose generator, with the output power changing as load (tissue plus cables) impedance **Z** changes. Load impedance **Z** (in ohms) is represented on the X-axis, and generator output power **P** (in watts) is represented on the Y-axis. In the illustrated embodiment, the electrosurgical power (RF) is set to 75 watts in a bipolar mode. As shown in the figure, the power will remain constant as it was set as long as the impedance **Z** stays between two cut-offs, low and high, of impedance, that is, for example, between 50 ohms and 300 ohms in the illustrated embodiment. Below load impedance **Z** of 50 ohms, the power **P** will decrease, as shown by the low impedance ramp **48**. Above load impedance **Z** of 300 ohms, the power **P** will decrease, as shown by the high impedance ramp **46**. Of particular interest to saline-enhanced electrosurgery is the low impedance cut-off (low impedance ramp **48**),

where power starts to ramp down as impedance **Z** drops further. This change in output is invisible to the user of the generator and not evident when the generator is in use, such as in an operating room.

FIG. 7 shows the general trend of how tissue impedance generally changes with time for saline-enhanced electrosurgery. As tissue heats up, the temperature coefficient of the tissue and saline in the cells is such that the tissue impedance decreases until a steady-state temperature is reached upon which time the impedance remains constant. Thus, as tissue heats up, the load impedance **Z** decreases, potentially approaching the impedance **Z** cut-off of 50 ohms. If tissue is sufficiently heated, such that the low impedance cut-off is passed, the power **P** decreases along the lines of the low impedance ramp **48** of FIG. **6**.

Combining the effects shown in FIG. **6** and FIG. **7**, it becomes clear that when using a general-purpose generator set to a "fixed" power, the actual power delivered can change dramatically over time as tissue heats up and impedance drops. Looking at FIG. **6**, if the impedance **Z** drops from 100 to 75 ohms over time, the power output would not change because the curve is "flat" in that region of impedances. If, however, the impedance **Z** drops from 75 to 30 ohms one would transgress the low impedance cut-off and "turn the corner" onto the low impedance ramp **48** portion of the curve and the power output would decrease dramatically.

According to one exemplary embodiment of the invention, the control device, such as flow rate controller **11**, receives a signal indicating the drop in actual power delivered to the tissue and adjusts the flow rate **Q** of saline to maintain the tissue/electrode interface at a desired temperature. In a preferred embodiment, the drop in actual power **P** delivered is sensed by the power measurement device **8** (shown in FIG. 1), and the flow rate **Q** of saline is decreased by the flow rate controller **11** (also shown in FIG. 1). Preferably, this reduction in saline flow rate **Q** allows the tissue temperature to stay as hot as possible without desiccation. If the control device was not in operation and the flow rate **Q** allowed to remain higher, the tissue would be over-cooled at the lower power input. This would result in decreasing the temperature of the tissue at the treatment site.

The flow rate controller **11** of FIG. 1 can be a simple "hard-wired" analog or digital device that requires no programming by the user or the manufacturer. The flow rate controller **11** can alternatively include a processor, with or without a storage medium, in which the determination procedure is performed by software, hardware, or a combination thereof. In another embodiment, the flow rate controller **11** can include semi-programmable hardware configured, for example, using a hardware descriptive language, such as Verilog. In another embodiment, the flow rate controller **11** of FIG. 1 is a computer, microprocessor-driven controller with

software embedded. In yet another embodiment, the flow rate controller **11** can include additional features, such as a delay mechanism, such as a timer, to automatically keep the saline flow on for several seconds after the RF is turned off to provide a post-coagulation cooling of the tissue or "quench," which can increase the strength of the tissue seal. Also, in another embodiment, the flow rate controller **11** can include a delay mechanism, such as a timer, to automatically turn on the saline flow several seconds before the RF is turned on to inhibit the possibility of undesirable effects as sticking, desiccation, smoke production and char formation. Also in another embodiment, the flow rate controller **11** can include a low level flow standby mechanism, such as a valve, which continues the saline flow at a standby flow level (which prevents the flow rate from going to zero when the RF power is turned off) below the surgical flow level ordinarily encountered during use of the electrosurgical device **5**.

As already mentioned herein, the saline can act as a shunt and divert energy away from target tissue. In order to describe the underlying issue of saline shunting, an exemplary bipolar endoscopic electrosurgical device according to the present invention will be described in some detail. While the bipolar electrosurgical device of the present invention is described with reference to use with the remainder of the system of the invention, it should be understood that the description of the combination is for purposes of illustrating the remainder of the system of the invention only. Consequently, it should be understood that the bipolar electrosurgical device of the present invention can be used alone, or in conjuction with the remainder of the system of the invention, or that, conversely, a wide variety of electrosurgical devices can be used in connection with the remainder of the system of the invention.

Preferably, the control device of the invention is used in connection with an electrosurgical device that is capable of controlling saline flow (for example, by controlling the location from which the saline is released from the electrosurgical device to the tissue). Any electrosurgical device that is capable of controlling saline flow is preferably used in connection with the invention described herein.

FIG. **8** shows an overall simple side schematic view of one exemplary embodiment of an electrosurgical device **5a** that is bipolar, and which is designed and configured to manipulate (e.g. grasp, coagulate and then cut) tissue. The electrosurgical device **5a** preferably includes an intermediate segment comprising a hollow shaft **17**, which is preferably connected to a tissue manipulator preferably comprising two opposing cooperating jaws **18a, 18b** located at the distal tip or end **53** of the shaft **17**. The electrosurgical device **5a** also preferably includes a collar **19** for rotating the entire shaft **17**, and connecting a proximal handle **20** at the proximal

end of the shaft **17**, an actuation mechanism **66** preferably comprising an actuation lever **21** and more preferably comprising a first-class lever (i.e. a lever with the fulcrum between the input force and the output force) which when squeezed will close the opposing jaws **18a, 18b**, a pair of paddles **22** to activate the built-in cutting mechanism **31** (not shown in the figure), and a cable **23** attached to and extending from the handle **20** that contains two electrical wires and one fluid channel which extend from the jaws **18a, 18b** through the shaft **17** and handle **20** (not shown individually in the figure).

In use, tissue to be treated is positioned between the jaws **18a, 18b** of the device **5a**. As shown in FIG. **9**, the hand grip portion **66a** of the actuation lever **21** is then moved in direction of arrow **58** and squeezed towards the handle **20** causing the lever **21** to rotate about a fixed axis or rotation provided by a pivot **66b**, and also causing the head portion **66c** of the lever **21** to move distally. Preferably, the actuation lever **21** is held about the pivot by a fixing mechanism comprising a pin **66d** extending through aligned holes in the actuation lever **21** and each side of the handle **20**. The lever **21**, is coupled, preferably mechanically, to an actuator **67** (i.e. a device which operates another device, in this case the jaws **18a, 18b**) which receives an input from the actuation mechanism **66**, here output displacement and/or force, from lever **21**, and operates the jaws **18a, 18b**.

More particularly, the actuator **67** preferably comprises a hollow elongated member **67a** mechanically coupled at the proximal end to the actuation lever **21** by an actuation mechanism connector **69**. The actuation mechanism connector **69** preferably comprises a spool configuration comprising a fixed distal flange **69a** and a fixed proximal flange **69b** separated by a spindle there between. As explained below, the distal flange **69a** and the proximal flange **69b** are fixed relative to the hollow elongation member **67a**.

Preferably, the spool comprises a two piece configuration with a distal spool portion **69c** comprising the distal flange **69a** and a first portion of the spindle **69d** and the proximal spool portion **69e** comprising the proximal flange **69b** and the second portion of the spindle **69f**. Preferably, the distal spool portion **69c** comprising the distal flange **69a** and a first portion of the spindle **69d** comprise a unitary piece, while the proximal spool portion **69e** comprising the proximal flange **69b** and the second portion of the spindle **69f** also comprise a unitary piece.

Preferably both the distal portion of the spool **69c** and the proximal portion of the spool **69e** are fixed relative to the hollow elongated member **67a** by being threaded over the proximal end **67b** of the hollow elongated member **67a** with internal threads for each hollow spool portion **69c, 69e** threadedly engaging external threads on the hollow elongated member **67a**. However, in other embodiments, at

least a portion of the actuation mechanism connector **69** (e.g. spool) may be unitarily formed with the actuator **67**, particularly elongated member **67a**, or the actuation mechanism connector **69** may be connected to the elongated member **67a** by, but not limited to welding, pining or press fitting.

Spindle **69d**, **69f** also preferably supports a movable flange **69g** thereon which slides along at least a portion of the spindle **69d**, **69f**. As shown in FIG. **9**, preferably a force manipulating member **69h**, preferably comprising a coil compression spring, is located between the distal flange **69a** and the movable flange **69g**. Also as shown in FIG. **9**, preferably, the head portion **66c** of the lever **21** is configured to mechanically couple with the actuation mechanism connector **69** by a yoke structure including two substantially parallel tabs **66e** extending on both sides of the spindle portion which engage the movable flange **69g** and the proximal flange **69b**. This structure of head portion **66c** and actuation mechanism connector **69** advantageously allows for the pivotable engagement of head portion **66c** with actuation mechanism connector **69**.

The distal end of the hollow elongated member portion of the actuator is preferably mechanically coupled to jaws **18a**, **18b** by a tissue manipulator connector **71**. The actuator **67**, and more particularly elongated member **67a**, and the tissue manipulator connector **71** may comprise a unitarily formed piece, or the tissue manipulator connector **71** may be connected to the elongated member **67a** by, but not limited to welding, threaded engagement, pining or press fitting.

Preferably, the tissue manipulator connector **71** comprises a bar portion **71a** extending distally and parallel from the distal end **67c** of the elongated member **67a** and a pivot pin portion **71b** which extends from the bar portion **71a** and perpendicular to the distal end **67c** of the elongated member **67a**.

As shown in FIG. **10**, the pivot pin portion **71b** of the tissue manipulator connector **71** for each jaw **18a**, **18b** preferably extends into a moving pivot hole **73**, with the axis of rotation for each moving pivot hole **73** configured parallel and of equal distance from the axis of rotation for a common fixed pivot hole **75** for each jaw **18a**, **18b**, the position of which is preferably being fixed by a pin **77** extending through the aligned holes in the jaws **18a**, **18b** and each opposite sides of shaft **17**.

For the above configuration, the mechanical advantage of the actuation lever is preferably in the range between and including 4:1 (i.e. 4 to 1) to 10:1. In other words, when a force of **25** lbf (111 Newtons) is applied to the hand grip portion **66a** of the actuation lever **21**, the force which may be exerted on the movable flange **69g** by head portion **66c** is typically in the range between and including 100 lbf (445 Newtons) to 250 lbf (1112 Newtons).

With use of the above configuration, as the head portion **66c** of the lever **21** moves distally from its extended or rest position, by virtue of the kinematics associated with substantially rigid mechanical components and couplings, the tabs **66e** on the head portion **66c** of the actuation lever **21** engage the movable flange **69g**, which displaces portions of the actuation mechanism connector **69**, the actuator **67**, and the tissue manipulator connectors **71** distally, and beings closing the jaws **18a, 18b**, by moving pivot pin **71b** in pivot hole **73** radially around fixed pivot pin **77** in fixed pivot hole **75**.

When compressible tissue is placed within the borders or confines of the jaws **18a, 18b**, as the jaws **18a, 18b** close the resistance to closure placed on the jaws **18a, 18b** by the tissue increases as the tissue compresses. In other words, the more the tissue is compressed, the greater the resistance to compression. While a certain amount of compression force of the tissue is desirable to seal the blood vessels of the tissue being treated, it is equally desirable not to place so much force on the tissue such that the blood vessels are split prior to treatment.

In light of the above, in configuring the operation of the tissue manipulator operating mechanism for opening and closing jaws **18a, 18b** as outlined above, a target force range was first established for the force to applied to the jaws **18a, 18b** at the moving pivot holes **73** by the distal movement of the mechanism. In order to provide enough force perpendicular to the surfaces **29a, 29b** of the jaws **18a, 18b** at the distal ends **55a, 55b** thereof for sealing, but without splitting tissue, an exemplary target force range for the force to applied to the jaws **18a, 18b** at each of the moving pivot holes **73** was about 65 lbf (289 Newtons) per hole to 90 lbf (400.3 Newtons).

In order to achieve the above, preferably force manipulating member **69h** comprises a coil compression spring which is preloaded to a exemplary first predetermined compression force of about 130 lbf (578.3 Newtons) and increases to a exemplary second predetermined compression force of about 180 lbf (800.7 Newtons) over an exemplary linear travel distance of the mechanism of about 3 mm.

As indicated above, as lever **21** travels distally from a first position, such as its extended or rest position, towards a second position, such as a latched position, the tissue manipulator operating mechanism described above is configured to correspondingly travel distally and close the jaws **18a, 18b**. One advantage of the aforementioned mechanism is that prior to the attaining of the first predetermined compression force (e.g. preload of the spring), the operating mechanism behaves in a substantially rigid manner and exhibits a force versus displacement curve with a steep slope. In other words, the force increases quickly for a given displacement of the mechanism. Consequently, the tissue manipulator operating mechanism may

attain the first predetermined compression force, and get into the target force range, with minimal distal travel of the tissue manipulator operating mechanism.

However, once the first predetermined compression force is attained, it is desirable to decrease the rate at which the force is further increased in order to attain the second (e.g. latched) position of the lever **21** prior to the force increasing beyond the second predetermined compression force. Thus, in the range between the first predetermined force and the second predetermined force, the rate of increase in the force is decreased as compared to the range between no force and the first predetermined force.

In the distal direction, the tissue manipulator operating mechanism draws the opposing jaws **18a, 18b** toward each other, to close the jaws **18a, 18b** on the tissue. However, when the actuation lever **21** is released, preferably the compression spring **69h**, which compresses during closing of the jaws **18a, 18b**, decompresses to apply an opening force of the jaws **18a, 18b** and force the elongated member **67a** and actuation lever **21** back to their jaw open position. Preferably, the elongated member **67a** acts on the jaws **18a, 18b** such that they open and close independently.

In other embodiments, the actuator may comprise, but is not limited to, other mechanical actuators or actuators such as electro-mechanical actuators, hydraulic actuators or pneumatic actuators (e.g. solenoids, motors, hydraulic pistons pneumatic pistons which may be coupled to the actuation mechanism and/or the tissue manipulator including, but not limited to, electrically, electromechanically, hydraulically or pneumatically. In one electromechanical embodiments, the actuation mechanism may comprise an electrical switch, the input from the actuation mechanism may comprise electric current and the actuation mechanism connector may comprise a wire conductor.

Once the jaws **18a, 18b** of the tissue manipulator are closed, RF energy and conductive fluid, such as saline, are then applied through the device **5a** and to the treatment site, thereby heating the tissue to coagulate, or achieve the desired treatment of the tissue. If desired, after coagulating the tissue between the jaws **18a, 18b**, the jaws **18a, 18b** can be held clamped together and the cutting mechanism **31** can be actuated to cut tissue.

FIG. **10** shows a schematic close-up section view of the two jaws **18a, 18b** at the distal tip or end **45** of the electrosurgical device **5a** at the distal end **53** of the shaft **17**. In one embodiment, each jaw **18a, 18b** includes energy-providing member, such as an electrode **25a, 25b**. In the embodiment of FIG. **10**, the energy-providing member shown is an elongated U-shaped energy-providing member with an elongated U-shaped manifold **24a, 24b** located beneath at least a portion of the energy-providing element and passing through the jaw **18a, 18b**, and at least one, or

as shown, a plurality of circular through holes or other fluid outlets **26a, 26b** provided through the electrode **25a, 25b**. Each jaw **18a, 18b** further includes a tissue manipulating jaw surface **29a, 29b** that contacts and grasps the tissue to be treated. In the embodiment illustrated in FIG. **10**, the jaw surface **29a, 29b** is textured, so that it is capable of grasping the tissue to be treated. However, the jaw surface **29a, 29b** need not be textured, and can include any type of desired surface configuration, such as serrations and the like, or can be provided with a smooth surface. In use, saline flows in a manifold **24a, 24b** (i.e. passage) in the direction of arrows **30a, 30b**, wherein the manifold **24a, 24b** may distribute saline flow relatively evenly (i.e., relatively uniformly) to the plurality of spaced holes **26a, 26b**, generally uniformly spaced, along the length of the electrode **25a, 25b** that are made in the electrode **25a, 25b** of the jaw **18a, 18b**. Preferably, electrode **25a, 25b** comprises an electrically conductive metal, which is preferably non-corrosive, such as stainless steel or titanium. Other metals include gold, silver, platinum, copper, aluminum and multi-layers thereof such as gold-plated copper. Holes **26a, 26b** of this exemplary embodiment preferably have a diameter in the range between and including about 0.10 mm to 2.0 mm and more preferably have a diameter in the range between and including about 0.15 mm to 0.020 mm.

Preferably, at least a portion (e.g. the portion of the jaw **18a, 18b** in direct contact with the electrode **25a, 25b** and the conductive fluid in the manifold **24a, 24b**) and, more preferably, most, if not all, of the structural material of each jaw **18a, 18b** comprises and is fabricated from a material that is non-conductive electrically. More preferably, the material comprises a non-conductive polymer such as polyamide (a/k/a nylon), polyphthalamide (PPA), polyamideimide (PAI), polyetherimide (PEI), polyetheretherketone (PEEK), polyphenylenesulfide (PPS), polysulfone (PSO), polyethersulfone (PES), syndiotactic polystyrene (SPS), polyimide (PI) or any other non-conductive polymer, thermoplastic or thermoset. In certain embodiments, the polymer may comprise a liquid crystal polymer and, more particularly, an aromatic liquid crystal polyester which is reinforced with glass fiber, such as Vectra® A130 from Ticona, 90 Morris Avenue, Summit, New Jersey 07901-3914. This non-conductive material, or insulator, is shown in the figure as reference number **27a, 27b**, and provides a combined housing for retaining the electrode **25a, 25b** and forming a portion of the manifold **24a, 24b**. Further, in some embodiments, the other portions of the jaw **18a, 18b** such as jaw surface **29a, 29b** can comprise and be fabricated from a non-conductive material.

In other embodiments, the non-conductive material of the jaw **18a, 18b** may comprise a non-conductive coating over an electrically conductive material. For example, the non-conductive coating may comprise a polymer coating applied over

an underlying metal, which is preferably non-corrosive, such as stainless steel or titanium.

As shown in FIG. **10**, each jaw **18a, 18b** may include a U-shaped groove **28a, 28b** that is recessed as to form a recess from the jaw tissue-manipulating surface **29a, 29b** to provide a fluid flow channel. In this embodiment, after the saline flows through the fluid exit holes **26a, 26b** from the manifold **24a, 24b**, it flows in the groove **28a, 28b**. When tissue is grasped or otherwise manipulated between the jaws, saline can flow in the groove **28a, 28b** between the electrode **25a, 25b** and the tissue, and exit through at least one exit groove **62a, 62b** that are open to the outside. Preferably, the electrode **25a, 25b** comprises at least a portion of the bottom wall of the groove **28a, 28b**. Where groove **28a, 28b** is not used, electrode **25a, 25b** may be level with and comprise at least a portion of jaw surface **29a, 29b**, or may protrude relative to jaw surface **29a, 29b**, or may completely comprise jaw surface **29a, 29b**.

As shown in FIGS. **10** and **12**, the fluid exit is formed in the portion of the jaw **18a, 18b** forming the outer wall **59a, 59b** of the exit groove **62a, 62b** and is located at the distal end **55a, 55b** of the jaws **18a, 18b**. However, in other embodiments, the fluid exit may be formed at any location along the length of the outer wall **59a, 59b**, or may be formed in the portion of the jaw **18a, 18b** forming the inner wall **61a, 61b** of the exit groove **62a, 62b**. Also as shown in FIG. **12**, a sensor, such as a temperature sensor, pressure sensor or saline impedance sensor for sensing the phase change associated with the onset of boiling may be located in outer wall **59a, 59b**. adjacent the electrode **25a, 25b** and/or the tissue.

FIG. **11** shows an overall schematic top view of the electrosurgical device **5a** shown in FIGS. **9** and **10**. Preferably, as shown in FIG. **11**, the jaws **18a, 18b** can be provided in a U-shaped loop configuration. In other words, the jaws **18a, 18b** can be formed such that the manifolds **24a, 24b**, electrodes **25a, 25b**, and/or grooves **28a, 28b** initially extend away from the proximal ends **57a, 57b** of the jaws **18a, 18b** towards the distal ends **55a, 55b** of the jaws **18a, 18b**, then return from the distal ends **55a, 55b** of the jaws **18a, 18b** towards the proximal ends **57a, 57b** of the jaws **18a, 18b** to form a U-shaped configuration.

FIG. **12** shows a close-up section top view of one of the loop jaws **18b** of the tip **45** of the electrosurgical device **5a**. In this embodiment, the jaws **18a, 18b** are provided in a loop configuration to create a space **47a, 47b** that allows a cutting mechanism **31** to move proximally and distally within the space **47a, 47b**. One can comprehend that the electrode configuration shown in FIG. **11** is simply an exemplary configuration, and the electrode need not be formed of two loops. For example, the electrosurgical device need not include a cutting mechanism, and the

electrodes in these embodiments would not be required to include a space or recess for passage of the cutting mechanism. The invention contemplates any suitable electrode configuration which may be used to treat tissue, particularly with RF energy and conductive fluid.

As shown in FIG, 12, jaws **18a, 18b** includes at least one tissue stop **95a, 95b**. In use, tissue stop **95a, 95b** inhibits tissue from extending within the confines of the jaw **18a, 18b** proximally past the end of electrode **25a, 25b** where it may not be treated.

Preferably jaws **18a, 18b** comprise an interchangeable configuration such that to jaws **18a, 18b** comprises the same components and can be used one for the other to reduce manufacturing costs and assembly complexity. However, in other embodiments, jaws **18a, 18b** may comprise different components and configurations.

As indicated above, electrodes **25a, 25b** of electrosurgical device **5a** are preferably electrically coupled to generator **6** via wire conductors of cable **9** contained in handle **20**. More specifically, one wire conductor, connected to electrode **25a**, for example, comprises the positive terminal while the other wire conductor, connected to electrode **25b**, for example comprises the negative terminal. The wire conductors **WC** are conductively attached, preferably via silver solder, to the electrodes **25a, 25b** at one end of the U-shaped configuration as shown in FIG. **12**.

If the saline that flows from one electrode **25a** to the other electrode **25b**, for example, is not boiling in any significant manner (e.g. saline temperature below the boiling temperature), a large fraction of the RF energy can be diverted away from target tissue. This "stealing" of RF energy tends to dramatically slow down the process of coagulating tissue and producing the desired hemostasis or aerostasis of the tissue. This situation is illustrated in FIG. **13**. In this embodiment, tissue **32** grasped between the jaws **18a, 18b** only partially occupies the jaw surface **29a, 29b** and does not fill the jaws **18a, 18b**. Areas **34** and **35** show areas of air between the jaws **18a, 18b**. Depending on orientation of the electrosurgical device **5a**, saline liquid may flow from the top electrode jaw **18a** to the lower electrode jaw **18b** in several locations, for example, at area **33**, located at the distal end **55a, 55b** of the jaws **18a, 18b**. Saline liquid may also flow from the top electrode jaw **18a** to the lower electrode jaw **18b** at locations between the distal end **55a, 55b** and proximal end **57a, 57b** of the jaws **18a, 18b** and in contact with the proximal end of the tissue **32** (relative to the user of the electrosurgical device **5a**), for example, at locations between tissue **32** and area **34**. Saline liquid may also flow from the top electrode jaw **18a** to the lower electrode jaw **18b** at locations adjacent the proximal end **57a,**

57b of the jaws **18a, 18b** and removed (i.e. not in contact) with the proximal end of the tissue **32**, for example, at locations between areas **34** and **35**. These locations of saline flow between areas **34** and **35** represent the closest gap between jaws (area **35**) and flow of saline along the tissue boundary **32**, which are the most likely areas for saline flow between the jaws **18a, 18b**. Since most of the saline is not boiled, excess saline **36** drips off the lower jaw.

The saline shunting scenario can also be explained by using an electrical circuit as shown in FIG. **14**. Electrically, the tissue and the saline fluid shunt can be modeled as resistors in parallel. Using Ohm's Law one can calculate the percentage of total RF power that is dissipated in the saline shunt as:

$$\% \text{ RF Power} = \frac{100}{[1 + R_s/R_t]}$$

In the embodiment illustrated in FIG. **14**, the total current (I) **50** from source **54** is split between two resistors, tissue electrical resistance (R_t), and saline shunt electrical resistance (R_s). This relationship is shown in the schematic graph of FIG. **15**, which shows the relationship of the ratio of saline to tissue resistance (R_s/R_t) (X-axis) to percent of power shunted into saline (Y-axis). As shown in the figure, when the resistance of the saline is equal to the tissue ($R_s/R_t = 1$), half the power is shunted into the saline. For example, when the resistance of the saline is four times that of the tissue, then only 20% of the power is shunted into the saline.

One benefit of the flow rate control strategy previously described herein, where a high % boiling is maintained, is that the flow of saline from, for example, one electrode **25a** to the other electrode **25b** is either eliminated altogether because all the flow boils off at the electrode/tissue interface between the electrode and the tissue, or a large fraction of the flow boils as it flows toward the other electrode. This second case is illustrated in FIG. **16**, that is, where a large fraction of the saline flow boils as it flows toward the other electrode. Note that in comparison to FIG. **13**, there is less saline flowing from the top jaw **18a** to the lower jaw **18b**, and where there is flow it is actively boiling, as indicated by the vapor bubbles shown in several locations **37** and **38**. According to the invention, boiling of a large fraction of the saline assures that most of the RF power will be directed into the tissue to achieve coagulation in the fastest time. Stated another way, another control strategy of the present invention is to reduce the presence of a saline shunt by increasing the % boiling of the saline.

Another aspect of the control strategy of the invention is that the flow of saline is preferably primarily directed spatially against or very near the target tissue **32** that is to receive the RF power. If the flow rate is not near where the RF power is

turned into heat, the saline is not capable of protecting the tissue **32** from desiccation by dissipating excess heat in the boiling process. Therefore, in a preferred embodiment, the flow of conductive fluid is directly primarily at the tissue treatment site.

With use of the electrosurgical device **5a**, typically a surgeon will grasp a small amount of tissue **32** with the very tip **45** of the device **5a** as shown in FIG. **17**. If the electrode jaws **18a, 18b** are long relative to the length of the tissue segment being grasped, resulting in tissue **32** being grasped only adjacent the distal ends **55a, 55b** of the jaws **18a, 18b**, then saline exiting of holes **26a, 26b** in the middle and adjacent the proximal end **57a, 57b** parts of the jaws **18a, 18b** may not be able to flow towards the distal end **55a** of the tip **45**, but may leak out along the upper jaw **18a**. Though surface tension of the upper surface **47** (i.e. facing the tissue) of the electrode **25a** and the geometry of the groove **28a** will act to keep saline flow in the groove **28a**, gravity can tend to cause the saline which has collected to overcoming the effects of surface tension and flow down directly to the opposing jaw **18b**. This would result in the undesirable effects mentioned above.

In another exemplary embodiment of the invention as shown by device **5b** in FIG. **17**, by providing two slidable gutters **39a, 39b**, the flow of saline can be collected and directed distally toward the tissue **32**. In this embodiment, the saline can flow from one jaw **18a** to the other jaw **18b** in areas **33**, located on each side of the tissue being grasped, but with a large percentage boiling before reaching the other jaw. According to this embodiment, the gutters **39a, 39b** can be fabricated from any material that is non-conducting, for example, such as the plastic and plastic coated metals which may be used for the jaws **18a, 18b** described above. The gutters **39a, 39b** can slide toward the distal end **55a, 55b** of the device **5a** as part of the activation of lever **21** shown in FIG. **8**, to be stopped automatically by the presence of tissue. Alternatively the gutters **39a, 39b** can be slid forward towards the distal ends **55a, 55b** as part of a separate mechanism action for moving the gutters **39a, 39b** proximally and distally, such as with a spring. In other words, a spring may be provided which, in the decompression direction, distally moves the gutters **39a, 39b** towards the distal ends **55a, 55b** of the jaws **18a, 18b** to cover the electrodes **25a, 25b**. Conversely, in the compression direction of the spring, the presence of the tissue **32** biases the spring and proximally moves the gutters **39a, 39b** towards the proximal ends **57a, 57b** of the jaws **18a, 18b**. The gutters **39a, 39b** can be fabricated from any suitable material that is non-conducting, for example, plastic.

FIG. **18** shows a schematic cross-sectional view of the gutters shown in FIG. **17**. The cross-section in FIG. **18** illustrates the nonconducting portion **27a, 27b** of

the jaw **18a, 18b**, the saline manifold **24a, 24b**, the electrodes **25a, 25b**, holes **26a, 26b**, groove **28a, 28b**, space **47a, 47b** for the cutting mechanism **31**, and gutters **39a, 39b**. Near the distal end **49a, 49b** of the gutters **39a, 39b**, exit grooves **62a, 62b** in the jaw **18a, 18b** can allow saline to flow through and onto the edge of the tissue **32** even if the gutter **39a, 39b** is pressed snuggly against the tissue **32** (shown in FIG. **10**).

Another exemplary embodiment of the invention as shown by device **5c** in FIGS. **19-21**. In this embodiment, similar to the preceding embodiment, the electrosurgical device also includes a mechanism for directing saline flow to where tissue is being heated using RF energy and providing a saline application mechanism which limits the application of saline to the area of the jaws **18a, 18b** as directed by the presence of the tissue **32**. Preferably, the mechanism for directing saline flow comprises one or more tissue activated valves **51a, 51b**. In FIGS. **19-20**, the jaw **18a, 18b** of the device **5c** includes a pin **40a, 40b** that is configured with a bulged portion **52a, 52b** in the middle section of the plunger pin **40a, 40b**, so that the pin **40a, 40b** can seat into a counter-sunk hole **26a, 26b** in the electrode **25a, 25b**. Pin **40a, 40b** preferably further includes a pin tip **41a, 41b** that contacts tissue. Preferably, the pin tip **41a, 41b** is rounded or atraumatic (i.e., blunt) to reduce tissue trauma. As illustrated in the figure, counter-sunk hole **26a, 26b** includes a recessed portion **56a, 56b** that is configured to receive the bulged portion **52a, 52b**, such that when seated within the recessed portion **56a, 56b**, the pin **40a, 40b** inhibits conductive fluid flow from the manifold **24a, 24b** to the tissue being treated. Preferably, a guide tube **42a, 42b** holds the pin **40a, 40b** in position, and spring **43a, 43b** provides decompression force to push the bulged portion **52a, 52b** of pin **40a, 40b** into the recessed portion **56a, 56b** and seal off the flow of saline from the manifold region **24a, 24b**. In use, the pin tip **41a, 41b** contacts tissue when the jaws **18a, 18b** compress tissue. When tissue is compressed, the tissue contacts the tip **41a, 41b** and overcomes the compression force of the spring **43a, 43b** which pushes the pin **40a, 40b** upwards, unseating the bulged portion **52a, 52b** of the pin **40a, 40b** from the recessed portion **56a, 56b**, and allowing saline to flow in direction of arrows **44a, 44b** through the annular space between the pin **40a, 40b** and the counter-sunk hole **26a, 26b**.

FIG. **21** shows a schematic view of one embodiment wherein a series of such tissue-activated valves **51a, 51b** functions to deliver saline flow only to areas of the jaws **18a, 18b** where tissue **32** is compressed and to be RF-heated. Referring to FIGS. **19-21**, tissue **32** is compressed in the area labeled **60**, and the holes **26a, 26b** are open to allow saline flow to the tissue treatment site. As described above, tissue contacts tip **41a, 41b**, thereby pushing pin **40a, 40b** upwards, unseating the bulged

portion **52a, 52b** of the pin **40a, 40b** from the recessed portion **56a, 56b** (shown in FIG. **20**). This interaction allows saline to flow from the device **5c** to the tissue **32** being treated. In the area labeled **63** in the figure, tissue is not compressed between jaws **18a, 18b** of the device **5c**, and therefore the holes **26a, 26b** are closed to the flow of saline from the device **5c**. Because the tips **41a, 41b** of pins **40a, 40b** do not contact tissue **32**, the pin **40a, 40b** is not forced from its seated position within recessed portion **56a, 56b** of the hole **26a, 26b** (shown in FIG. **19**).

In addition to providing a saline application mechanism which limits the application of saline to the area of the jaws as directed by the presence of the tissue, gutters **39a, 39b** and pins **40a, 40b** may provide an output related to the magnitude of a tissue within the jaws and, in doing so, be used as part of a mechanism to determine the dimensions, area or volume of the tissue located within the confines of the jaws.

It has been found that the volume of tissue within the confines of the jaws is directly related to, and may be correlated to, an estimated tissue treatment time period. Consequently, where the volume of tissue within the confines of the jaws is known, a predetermined treatment time period is also known from the established correlation. Consequently, during surgery, the actual tissue treatment time period may be compared to a predetermined tissue treatment time period, which is stored for example, in the memory of a microprocessor or on a printed table. Then, when the actual tissue treatment time period is determined to be equal to or greater than the predetermined tissue treatment time period, the user of the electrosurgical device is informed that the predetermined tissue treatment time period has been reached or exceeded, and can move to a new tissue treatment site.

In considering the width of the tissue within the confines of the jaw **18a, 18b**, as shown in FIG. **12**, the width **W** of the tissue can be approximated as being equal the width of the jaw **18a, 18b** as, in a vast majority of instances, the tissue treatment site will span the width of the jaw **18a, 18b**. An exemplary width **W** is about 8 mm or less.

In considering the length of the tissue **32** within the confines of the jaws **18a, 18b**, as indicated above, the length **L** can be determined by comparing, for example, the location of the distal end **49a, 49b** of gutter **39a, 39b** relative to the distal end **55a, 55b** of jaw **18a, 18b**. When the distal end **49a, 49b** of gutter **39a, 39b** extends to the distal end **55a, 55b** of jaw **18a, 18b**, the tissue length within the confines is equal to zero. Then, as the distal end **49a, 49b** of gutter **39a, 39b** retracts proximally away from the distal end **55a, 55b** of jaw **18a, 18b** due to the interference of tissue **32**, the linear displacement between the distal end **49a, 49b** of gutter **39a, 39b** and

the distal end **55a, 55b** of jaw **18a, 18b** comprises the length **L** of the tissue **32**. An exemplary length of tissue is about 30 mm or less.

The measurement of linear displacement between the distal end **49a, 49b** of gutter **39a, 39b** and the distal end **55a, 55b** of jaw **18a, 18b** may be correlated, preferably mechanically, to a measurement scale, such as a dimensional scale (e.g. ruler) or time scale preferably located on the device **5a**, such as on the side of the gutter **39a, 39b** or the jaw **18a, 18b** or the handle. The measurement may be unitless or comprise an input for tissue dimension (e.g. length), tissue area or tissue volume. Alternatively, the linear displacement may be electromechanically correlated to a measurement scale by, for example, a linear sensor, such as a linear transducer, wherein an electrical output signal corresponding to linear displacement is stored in the memory of a microprocessor and manipulated by an algorithm to provide measurements of linear displacement.

Once the length of the tissue **32** within the confines of the jaws **18a, 18b** is known, the area of tissue within the confines of the jaws **18a, 18b** and perpendicular to the jaw surfaces **29a, 29b** may be determined via geometry as shown in FIG. **22**. More specifically, in the situation, for example, where jaws **18a, 18b** are held about a common pivot, such as provided by pin **77**, simple calculations involving the area of triangles may be performed to determine the area of tissue in question. For example, as shown in FIG. **22**, jaws **18a, 18b** are preferably angularly positioned equally about the pivot's axis of rotation from their fully closed position forming a first upper and lower right triangles, each with a hypotenuse extending from the axis of rotation to the distal ends **55a, 55b** of each of the jaws **18a, 18b**. Within the area of each first upper triangle and first lower triangle are two smaller second upper and lower right triangles, each with a hypotenuse extending from the axis of rotation to the distal ends **49a, 49b** of the gutters **39a, 39b**. The area of the tissue within the confines of the jaws **18a, 18b** can then be determined by subtracting the area of each of the second smaller upper and lower right triangles, which are void of tissue **32**, from the area of each of the first larger upper and lower right triangles, respectively, with the remaining area representing the area of the tissue.

In order to determine the area of each of the first and second upper and lower right triangles as described above, preferably the length of each hypotenuse for each triangle is known along with the angular displacement of the jaws **18a, 18b** from their fully closed position. With regards to the length of the hypotenuse for each of the first larger upper and lower triangles, the length of the hypotenuse is fixed by the length between the distal end **55a, 55b** of jaw **18a, 18b** and the pivot's axis of rotation, here, pin **77**. An exemplary length is about 45 mm. With regards to the length of the hypotenuse for each of the first smaller upper and lower triangles, the

length of each hypotenuse may be determined by subtracting the length of the tissue L as determined above from the length of hypotenuse for each of the first larger upper and lower triangles. As indicated above an exemplary length of tissue is about 30 mm. Consequently, where exemplary length of the hypotenuse for the first upper and lower triangles equals 45 mm, the length of the hypotenuse for each of the first smaller upper and lower triangles is about 15 mm (i.e. 45 mm – 30 mm).

With regards to the angular displacement of the jaws **18a, 18b** from their fully closed position, an exemplary angular displacement is about 6 degrees or less per jaw **18a, 18b**. In an exemplary embodiment, jaws **18a, 18b** are configured to provide an angular displacement of about 20 degrees per side, as in the case where both jaws **18a, 18b** open and close, for a total angular displacement capability of about 40 degrees or less.

With an exemplary tissue length of 30 mm, an exemplary angular displacement of the jaws **18a, 18b** of 6 degrees per side and an exemplary length between the distal end **55a, 55b** of jaw **18a, 18b** and the pivot's axis of rotation of 45 mm, the cross-sectional area of the tissue is estimated to comprise about 187 mm^2 (1.87 cm^2). With regards to volume, with an exemplary jaw width of 8 mm, the volume of tissue within the confines of the jaws **18a, 18b** comprises about 1496 mm^3 (1.496 cm^3).

Given that jaws **18a, 18b** are mechanically coupled to elongated member **67a**, the angular position of the may be correlated to the linear distal displacement of elongated member. Thus, similar to gutters **39a, 39b**, the linear displacement of the elongated member **67a** may be correlated to a measurement scale. Furthermore, the measurement scale preferably considers both the length **L** of the tissue **32** and the angular position of the jaws. As shown in FIG. **23**, in one exemplary embodiment the length **L** of tissue **32** within the confines of the jaws may be correlated to a percentage, such as 25%, 50% and 100% of jaw length, with the percentage readable or otherwise detectable, by the user of the device on the device, such as the side of the jaws **18a, 18b**, for example. The given percentages may then be expressed in the form of concentric circles **96a-c** forming a multi-dimensional dial scale **96d** for a dial gauge **96** preferably located on the device. Thus, the a reading of the percentage of jaw length (which correlates to tissue length **L**) on the side of the jaws **18a, 18b** may be directed correlated to one of the dial scales **96d** on the device.

With respect to the dial **96e** of the dial gauge **96**, the position of the dial **96e** may be directly correlated to the position of the elongated member **67a** (which is directly correlated to the angular position of the jaws **18a, 18b**) via a rack and pinion. For example, as shown in FIG. **24**, the rack **96f** may be located on elongated member **67a** which engages a pinion **96g** to which dial **96e** is connected. Thus, the

displacement of elongated member **67a** may be correlated to the position of the dial **96e** of the dial gauge **96**. Preferably, the dial scales **96d** are correlated to an approximation of the time required to treat the tissue **32**, rather than the volume of tissue within the confines of the jaws **18a, 18b**. In this manner, the user of the device **5a** may correlate the tissue treatment time approximated on the device **5a** with an actual timing device, such as a clock, to establish when the actual time elapsed for tissue treatment time has met or exceeded the approximated tissue treatment time provided by the device **5a**.

Generally, substantially linear through holes **26a, 26b** of the electrode **25a, 25b** supply conductive fluid to the treatment site. However, in an alternative embodiment shown as device **5d** in FIG. **25**, these holes are provided in the form of porous material such as metal. In this embodiment, the electrodes **25a, 25b** preferably do not include discrete substantially linear holes through a solid non-porous material; rather, the electrode **25a, 25b** and the electrode surface itself are made porous by a tortuous path to allow infusion of the fluid to the treatment site. Porous sintered metal is available in many materials (such as, for example, 316L stainless steel, titanium, Ni-Chrome, and the like) and shapes (such as cylinders, discs, plugs, and the like) from companies such as Porvair, located in Henderson, NC.

Porous metal components can be formed by a sintered metal powder process or by injection molding a two-part combination of metal and a material that can be burned off to form pores that connect (open cell) to each other. With sintering, for example, typically solid particles of material are placed in a mold under heat and pressure such that the outer surface of the particles soften and bond to one another with the pores comprising the interstices between the particles. Alternatively, when porosity is formed by burning off material, it is not the interstice between the particles which provides the porosity as with sintering, but rather a partial evisceration of the material generally provided by the removal of a component with a lower melt temperature than the burn off temperature.

In this embodiment, fluid will flow out of the electrode **25a, 25b** everywhere the pores are open. Preferably, the exterior (that is, the portions of the components **25a, 25b** that do not comprise the portion of the device **5d** involved in tissue treatment) of such porous metal electrode components **25a, 25b** can be covered with a material, such as a polymer coating, that fills the pores and inhibits both the flow of saline and the passing of electrical energy. Alternatively, the device **5d** can include gutters **39a, 39b** to inhibit the flow of saline in areas where it is desired to inhibit saline flow.

In yet another embodiment, a porous polymer is used in place of the porous metal. Although the polymer is generally non-conductive, a conductive fluid provided will conduct the RF energy across the porous polymer wall and to the tissue to be treated. Suitable materials include high temperature open cell silicone foam and porous polycarbonates, among others. Different from sintering or evisceration of material, formation of porosity in open cell polymer foams is typically accomplished by the introduction of gas bubbles, either chemically or physically, into the polymer during its formation or melt phase which form a cellular structure. However, sintering or evisceration of material may also be used with polymer materials.

Porous ceramics also generally fall into the category of being non-conductive, since they could distribute conductive fluid flow, withstand high temperatures and be machinable or moldable for manufacturing purposes. Preferably, the material used transmits both fluid flow and electrical energy; thus, materials with properties between high-electrical conductivity metals and low electrical conductivity polymers are also contemplated, such as porous carbon-filled polymers. In these embodiments, fluid is distributed along the length of the electrodes, where porous material is used to fabricate the electrodes. All or a portion of the electrodes can be porous according to the invention.

Preferably the holes **26a, 26b** in the porous material have a pore size (cross-sectional dimension) in the range between and including about 2.5 micrometers (0.0025 mm) to 500 micrometers (0.5 mm) and more preferably has pore size in the range between and including about 10 micrometers (0.01 mm) to 120 micrometers (0.12 mm). Even more preferably, the porous material has a pore size in the range between and including about 20 micrometers (0.02 mm) to 80 micrometers (0.08 mm).

As discussed above, exit grooves **62a, 62b** of jaws **18a, 18b** provide a fluid exit from the jaws **18a, 18b** that is open to the outside of the jaws **18a, 18b**. In an alternative embodiment, rather than discrete openings, the fluid exits from the jaws may be provided in the form of a porous structure as part of, for example, a porous material (such as metal, polymer or ceramic discussed above). For example, as shown for device **5e** in FIG. **26**, preferably a least a wall portion **64a, 64b** of the outer wall **59a, 59b** of jaw **18a, 18b** of device **5e** may comprise the porous material. As shown, porous material of outer wall **64a, 64b** has an inlet surface which comprises a side surface of the fluid flow channel provided by recess **28a, 28b** and an outlet surface **56a, 65b** which comprises a non-tissue-manipulating surface. Furthermore, the porous material also preferably comprises an additional fluid outlet surface comprising a tissue-manipulating surface **29a, 29b**. The inlet surface and

the outlet surface are connected by a plurality of tortuous paths in the porous material.

As shown, the porous material preferably terminates on the non-tissue-manipulating surface **65a, 65b** distally away or remote from the tissue treatment site and tissue **32** such that the porous material fluid outlet surfaces may only partially be in contact with tissue **32** (i.e. tissue-manipulating surface **29a, 29b** is in contact with tissue **32**). If the complete fluid outlet surfaces of the porous material are in contact and become covered by tissue **32** with use, the pores of the porous material may become obstructed and no longer function as exits for fluid. As shown wall portion **64a, 64b** also comprises at least a portion of the jaw surface **29a, 29b** in contact with tissue **32** during treatment thereof. Also as shown, the porous material may at least partially overlie the electrode **25a** as shown by jaw **18a**. Also alternatively as shown, the porous material may comprise a least a wall portion of the inner wall **61a, 61b** of jaw **18a, 18b** of device **5e**.

Preferably the porous material provides for the wicking (i.e. drawing in of fluid by capillary action or capillarity) of the fluid into the pores of the porous material. In order to promote wicking of the fluid into the pores of the porous material, preferably the porous member also comprises a hydrophilic material, which may be provided, for example, by the porous material itself with or without post treating (e.g. plasma surface treatment such as hypercleaning, etching or micro-roughening, plasma surface modification of the molecular structure, surface chemical activation or crosslinking), or by a coating provided thereto, such as a surfactant.

In addition to providing a more uniform distribution of fluid exits in the jaw **18a, 18b**, the porous material of wall portion **64a, 64b** also provides other advantages. For example, discrete openings such as exit groove **62a, 62b** are difficult to mold or machine below a size of 0.276 millimeters (0.007 inches). Conversely, the porous material may provide exits of a smaller dimension. Furthermore, once exit groove **62a, 62b** becomes filled with fluid, a surface tension flow barrier may be created by the fluid within the exit groove **62a** inhibiting flow of additional fluid. Conversely, fluid may be conveyed in the porous material and away from groove **28a, 28b** by wicking as described above.

In addition to providing exits for fluid along the outer surface **65a, 65b** of the outer wall **59a, 59b**, and outside the confines of the jaw **18a, 18b**, the porous material also provides exits for fluid on jaw surfaces **29a, 29b** which grasp or otherwise manipulate tissue **32**. Consequently, because heated and/or electrified fluid can now be provided to jaw surface **29a, 29b**, heat and/or electric current

which may flow though the fluid (in the case of a conductive fluid) results in a wider tissue sealing region as compared to when the jaw surfaces do not dissipate fluid.

In addition to the above, when jaw surfaces **29a, 29b** in contact with tissue **32** dissipate fluid, tissue **32** is less apt to stick to the jaw surfaces as compared to the situation where the jaw surfaces do not dissipate fluid. Furthermore, the roughness of the porous material may reduce the need for serrations of the jaw surface **29a, 29b** (and the associated tissue damage) to adequately grasp the tissue **32**.

Preferably, the wall portion **64a, 64b** is joined to the remainder of the jaw **18a, 18b** by an adhesive. Preferably, the adhesive comprises a thermoset polymer, and more preferably a thermoset one-component epoxy adhesive from Engineered Material Systems Inc. of Delaware Ohio sold under the designation EMS 502-09. In other embodiments, the adhesive may comprise a thermoplastic polymer. In still other embodiments wall portion **64a, 64b** may be joined to the remainder of the jaw **18a, 18b** by methods of joining other than adhesive bonding with a separate adhesive. For example, wall portion **64a, 64b** may be autogenicly bonded to the remainder of the jaw **18a, 18b**. In other words, bonded where the bonding substance comprises the material of the wall portion **64a, 64b** and/or jaw **18a, 18b** themselves, as apposed to the use of separate materials such as adhesives.

In order to achieve autogenic bonding of the wall portion **64a, 64b** with the jaw **18a, 18b**, preferably an interface (e.g. contact location) between the two materials is subjected to heat and pressure. By application of heat and pressure to the wall portion **64a, 64b** and/or jaw **18a, 18b**, at least the surface portion of the wall portion **64a, 64b** and/or jaw **18a, 18b** subjected to the heat softens and/or melts to give it adhesive properties. Typically, a thin layer of polymer melt (where at least one of the wall **64** of jaw **18** comprises a polymer) on at least one of the surfaces to be joined is created, at which time the wall portion **64a, 64b** and jaw **18a, 18b** may be pressed together. This material is subsequently cooled and bonds the surfaces, at which time the clamping force removed.

The above description may be more appropriately characterized as thermal autogenic bonding. In other words, autogenic bonding is achieved by the application of heat to at least one of the items to be bonded. Furthermore, the temperature at which thermal autogenic bonding occurs may be referred to as the "thermal autogenic bonding temperature".

Autogenic bonding may also be performed without heat, for example, by means of a suitable solvent applied to the item(s) to be bonded which "soften" the bonding surface. Adhesion is attained by evaporation of the solvent, absorption of it into adjacent material, and/or diffusion of liquefied polymer molecules or chain segments across the interface.

In addition to adhesive and autogenic bonding, it should be understood that joining of the wall portion **64a, 64b** and jaw **18a, 18b** may be accomplished by any suitable method, autogenic or not, such as, but not limited to, vibration welding, ultrasonic welding, high-frequency welding, electromagnetic welding, induction welding, friction welding, hot-gas welding, hot-plate welding, heat staking, adhesive bonding, or mechanical fastening, such as with mechanical fasteners comprising screws.

As previously indicated herein, the presence of a fluid coupling at the electrode/tissue interface inhibits such undesirable effects as sticking, desiccation, smoke production and char formation. However, as also previously indicated herein, an uncontrolled flow rate of fluid can provide too much cooling at the electrode/tissue interface and increase tissue treatment time, which is also undesirable. Thus, the amount of fluid present at the electrode/tissue interface must be balanced against competing considerations. As shown in FIG. **18**, as well as other embodiments, the width of groove **28a, 28b** is greater than the depth of the groove **28a, 28b**. Preferably this aspect ratio of width of the groove to depth of the groove is always greater than or equal to 1.0 to better to ensure that the tissue is not so separated from the electrode **25a, 25b** that too much energy is lost in the fluid coupling therebetween. An exemplary width of the groove is greater than about 0.04 inches while an exemplary depth of the groove is less than about 0.03 inches.

In further seeking to balance competing interests, as previously indicated, the fluid flow channel above the electrode **25a, 25b** may be eliminated and the electrode **25a, 25b** may be level with and comprise at least a portion of the jaw surface **29a, 29b**. As shown for the embodiment **5f** of FIGS. **27-31**, electrode **25a, 25b** is configured to be a substantially flush with the surrounding outer and inner portion of the tissue manipulating jaw surface **29a, 29b**. More specifically, as best shown in FIG. **29**, electrode **25a, 25b** is configured to be flush with the surrounding portion of the tissue manipulating jaw surface **29a, 29b**. However, due to manufacturing tolerances, electrode **25a, 25b** may actually be in the range between and including about $\pm$ 0.010 inches above or below the surrounding outer and inner portions of the tissue manipulating jaw surface **29a, 29b**.

In the case where the groove **28a, 28b** and corresponding fluid flow channel above the electrode **25a, 25b** has been eliminated, as for device **5f**, tissue **32** overlying the electrode **25a, 25b** now will have substantially increased intimate contact with the electrode **25a, 25b**. Given this increase in intimate contact with the electrode **25a, 25b**, the fluid provided from the device **5f** may more preferably comprise an electrically non-conductive fluid as previously discussed herein. In this manner, none of the electrical current provided from the electrode **25a, 25b** is lost

through the fluid and the shunting problem previously identified herein is eliminated.

With the elimination of the groove **28a, 28b** and corresponding fluid flow channel above the electrode **25a, 25b**, the fluid outlet holes **26a, 26b** extending through the electrode **25a, 25b** may be more apt to become blocked by tissue **32** which overlies the surface of the electrode **25a, 25b**. With this occurrence, the inability of the fluid to flow from the holes **26a, 26b** may cause the fluid beneath the electrode **25a, 25b** to boil resulting in counter pressure to flow from the manifold **24a, 24b** which is undesirable. Consequently, preferably jaw **18a, 18b** is provided with at least one fluid outlet remote from the tissue manipulating jaw surface **29a, 29** and preferably provided in a location substantially inaccessible to direct contact with tissue or otherwise configured away from direct contact with tissue as to not become occluded by tissue with use of device **5f**. As shown in FIGS. **27-31**, jaw **18a, 18b** is provided with such a fluid outlet in the form of fluid outlet **82a, 82b** located on the proximal end of jaw **18a, 18b**. Furthermore, as shown, outlet **82a, 82b** is sheltered by shaft **17** and tissue stop **95a, 95b**.

With the elimination of the groove **28a, 28b** and corresponding fluid flow channel above the electrode **25a, 25b**, the amount of fluid between the surfaces of the electrode **25a, 25b** may also be substantially decreased. While fluid from the proximal fluid outlet **82a, 82b** may still wet the surface of the electrode **25a, 25b** when device **5f** is used with the tip pointed downward relative to the handle **20**, the elimination of groove **28a, 28b** may still decrease the amount of fluid at the interface. In order to inhibit sticking of tissue to the electrode **25a, 25b**, preferably the manifold **24a, 24b** is configured to transfer heat from jaw **18a, 18b** and particularly the electrode **25a, 25b** to the fluid flowing in the manifold **24a, 24b** to maintain the temperature of the electrode surface in the range between and including about 70 °C to 120 °C during the surgical procedure and more particularly in the range between and including about 80 °C to 100 °C.

Rather than having a sharp outer edge as with certain embodiments disclosed herein, the outer perimeter edges of tissue manipulating jaw surfaces **29a, 29b** may comprise bevel edges to inhibit inadvertent cutting of tissue or reduce trauma thereon. Furthermore, the beveled edges are configured to further concentrate a great majority of the force and electrical power converted to heat in the tissue located in the medial portion of grasping surfaces adjacent electrodes **25a, 25b**.

Preferably the relationship between the surface of electrode **25a, 25b** and fluid from the fluid source 1 throughout the various embodiments should be such that the fluid wets the surface of the electrode **25a, 25b** to form a continuous thin film coating thereon when the electrode **25a, 25b** is not clamped on tissue and does

not form isolated rivulets or circular beads on the surface of the electrode **25a, 25b.** Contact angle, θ, is a quantitative measure of the wetting of a solid by a liquid. It is defined geometrically as the angle formed by a liquid at the three phase boundary where a liquid, gas and solid intersect. In terms of the thermodynamics of the materials involved, contact angle θ involves the interfacial free energies between the three phases given by the equation $\gamma_{LV} \cos\theta = \gamma_{SV} - \gamma_{SL}$ where γ_{LV}, γ_{SV} and γ_{SL} refer to the interfacial energies of the liquid/vapor, solid/vapor and solid/liquid interfaces, respectively. If the contact angle θ is less than 90 degrees the liquid is said to wet the solid. If the contact angle is greater than 90 degrees the liquid is non-wetting. A zero contact angle θ represents complete wetting. Thus, preferably the contact angle is less than 90 degrees.

For clarification, while it is known that the contact angle θ may be defined by the preceding equation, in reality contact angle θ is determined by a various models to an approximation. According to publication entitled "Surface Energy Calculations" (dated September 13, 2001) from First Ten Angstroms (465 Dinwiddie Street, Portsmouth, Virginia 23704), there are five models which are widely used to approximate contact angle θ and a number of others which have small followings. The five predominate models and their synonyms are: (1) Zisman critical wetting tension; (2) Girifalco, Good, Fowkes, Young combining rule; (3) Owens, Wendt geometric mean; (4) Wu harmonic mean; and (5) Lewis acid/base theory. Also according to the First Ten Angstroms publication, for well-known, well characterized surfaces, there can be a 25% difference in the answers provided for the contact angle θ by the models. Also for clarification, any one of the five predominate models above which calculates a contact angle θ within a particular range of contact angles θ or the contact angle θ required of a particular embodiment of the invention should be considered as fulfilling the requirements of the embodiment, even if the remaining four models calculate a contact angle θ which does not fulfill the requirements of the embodiment.

While the invention insofar has been described in relation to a bipolar electrosurgical device, it will be readily apparent that other electrosurgical devices can be easily adapted to be used in connection with the invention. For example, the electrosurgical device may be provided as a monopolar device. In this embodiment, one of the wires going to the bipolar device would instead go to a ground pad dispersive electrode located on the patient's back or other suitable anatomical location. Minimally, the electrosurgical device will be capable of delivering RF power and fluid to tissue. For example, the device can comprise a straight needle having an interior lumen for transmitting fluid to the tissue. Alternatively, the

electrosurgical device can comprise other configurations such as loops, forceps, blades, and the like.

Other suitable electrosurgical devices that can be used in connection with the invention described herein include, but are not limited to, devices described in U.S. Patent Application Serial No. 09/668,403 (filed 22 September 2000), U.S. Patent No. 5,897,553 entitled "Ball Point Fluid-Assisted Electrocautery Device to Mulier et al., U.S. Patent No. 6,063,081 entitled "Fluid-Assisted Electrocautery Device to Mulier et al., and U.S. Patent No. 6,096,037 entitled "Tissue Sealing Electrosurgery Device and Methods of Sealing Tissue to Mulier et al.

One or more of the features of the previously described system can be built into a custom RF generator. This embodiment can provide one or more advantages. For example, this type of system can save space and reduce overall complexity for the user. This system can also enable the manufacturer to increase the power delivered into low impedance loads, thereby further reducing the time to achieve the desired tissue effects. This changes the curve of FIG. 5, by eliminating or reducing the slope of the low impedance ramp **48** of power versus impedance.

To effectively treat thick tissues, it can be advantageous to have the ability to pulse the RF power on and off. Under some circumstances, the temperature deep in tissue can rise quickly past the 100 °C desiccation point even though the electrode/tissue interface is boiling at 100 °C. This manifests itself as "popping," as steam generated deep in the tissue boils too fast and erupts toward the surface. In one embodiment of the invention, a switch is provided on the control device or custom generator to allow the user to select a "pulse" mode of the RF power. Preferably, the RF power system in this embodiment is further controlled by software.

In some embodiments, it can be desirable to control the temperature of the conductive fluid before it is released from the electrosurgical device. In one embodiment, a heat exchanger is provided for the outgoing saline flow to either heat or chill the saline. The heat exchanger may be provided as part of the electrosurgical device or as part of another part of the system, such as within the enclosure **14**. Pre-heating the saline to a predetermined level below boiling reduces the transient warm-up time of the device as RF is initially turned on, thereby reducing the time to cause coagulation of tissue. Alternatively, pre-chilling the saline is useful when the surgeon desires to protect certain tissues at the electrode/tissue interface and treat only deeper tissue. One exemplary application of this embodiment is the treatment of varicose veins, where it is desirable to avoid thermal damage to the surface of the skin. At the same time, treatment is provided to shrink underlying blood vessels using thermal coagulation. The temperature of

the conductive fluid prior to release from the surgical device can therefore be controlled, to provide the desired treatment effect.

In another embodiment, the flow rate controller is modified to provide for a saline flow rate that results in greater than 100% boiling at the tissue treatment site. For example, the selection switch **12** of the flow rate controller **11** (shown in FIG. 1) can include settings that correspond to 110%, 120% and greater percentages of boiling. These higher settings can be of value to a surgeon in such situations as when encountering thick tissue, wherein the thickness of the tissue can increase conduction away from the electrode jaws. Since the basic control strategy neglects heat conduction, setting for 100% boiling can result in 80% of 90% boiling, depending upon the amount of conduction. Given the teachings herein, the switch of the flow rate controller can accommodate any desirable flow rate settings, to achieve the desired saline boiling at the tissue treatment site.

Some embodiments of the invention can provide one or more advantages over current electrosurgical techniques and devices. For example, the invention preferably achieves the desired tissue effect (for example, coagulation, cutting, and the like) in a fast manner. In a preferred embodiment, by actively controlling the flow rate of saline, both in quantity (Q vs. P) and location (for example, using gutters to direct fluid distally to tissue, using holes to direct flow of fluid, or other similar methods) the electrosurgical device can create a hot non-desiccating electrode/tissue interface and thus a fast thermally induced tissue coagulation effect.

The use of the disclosed devices can result in significantly lower blood loss during surgical procedures such as liver resections. Typical blood loss for a right hepatectomy can be in the range of 500 – 1,000 cubic centimeters. Use of the devices disclosed herein to perform pre-transection coagulation of the liver can result in blood loss in the range of 50 – 300 cubic centimeters. Such a reduction in blood loss can reduce or eliminate the need for blood transfusions, and thus the cost and negative clinical consequences associated with blood transfusions, such as prolonged hospitalization and a greater likelihood of cancer recurrence. Use of the device can also provide improved sealing of bile ducts, and reduce the incidence of post-operative bile leakage, which is considered a major surgical complication.

The use of the devices as disclosed herein can result in a lower frequency of post-operative air leaks after lung resection, compared with linear staplers. This reduction in air leaks can reduce the length of hospitalization and the length of time that a chest tube must remain in place. The use of the devices disclosed herein can also reduce the frequency of expectorated staples (staples coughed up by the patient), since no foreign body is needed to seal lung tissue against air leaks and blood loss. The use of the devices disclosed herein can also speed up and simplify

the histopathological examination of lung tissue removed for biopsy as part of a wedge resection, since the pathologist does not have to carefully remove dozens of small staples from the tissue sample.

The invention can, in some embodiments, deliver fast treatment of tissue without using a temperature sensor built into the device or a custom special-purpose generator. In a preferred embodiment, there is no built-in temperature sensor or other type of tissue sensor, nor is there any custom generator. Preferably, the invention provides a means for controlling the flow rate to the device such that the device and flow rate controller can be used with a wide variety of general-purpose generators. Any general-purpose generator is useable in connection with the fluid delivery system and flow rate controller to provide the desired power; the flow rate controller will accept the power and constantly adjust the saline flow rate according to the control strategy. Preferably, the generator is not actively controlled by the invention, so that standard generators are useable according to the invention. Preferably, there is no active feedback from the device and the control of the saline flow rate is "open loop." Thus, in this embodiment, the control of saline flow rate is not dependent on feedback, but rather the measurement of the RF power going out to the device.

In another aspect, the invention preferably provides an electrosurgical device design that is capable of quickly and effectively sealing a wide variety of tissue segment sizes. The electrosurgical device provides a number of characteristics that improve the ability to treat a wide variety of tissue size and thickness. For example, a preferred embodiment provides the ability to control the saline flow towards a high percentage boiling, for example, 80 – 100%. This reduces shunting of the RF by boiling off saline before it could flow to the other electrode, or by boiling the saline as it is in the process of flowing to the other electrode. In another aspect, one preferred embodiment includes gutters in connection with the electrodes. In this embodiment, saline flow is directed toward the tissue treatment site, thereby providing all or substantially all of the conductive fluid to the treatment site. Thus, the tissue being treated is sufficiently "protected" from desiccation by utilizing the controlled conductive fluid boiling described herein. Preferably, the tissue-activated jaws offer another way to provide the conductive fluid in proximity to where the RF power is turned into heat.

For purposes of the appended claims, the term "manipulate" includes, but is not limited to, the functions of grasping, holding, fixing, cutting, dissecting, exposing, removing, extracting, retrieving, coagulating, ablating and otherwise manipulating or similarly treating tissue. Also for purposes of the appended claims, the term "tissue" includes, but is not limited to, organs (e.g. liver, lung, spleen,

gallbladder), highly vascular tissues (e.g. liver, spleen), soft and hard tissues (e.g. adipose, areolar, bone, bronchus-associated lymphoid, cancellous, chondroid, chordal, chromaffin, cicatricial, connective, elastic, embryonic, endothelial, epithelial, erectile, fatty, fibrous, gelatiginous, glandular, granulation, homologous, indifferent, interstitial, lymphadenoid, lymphoid, mesenchymal, mucosa-associated lymphoid, mucous, muscular, myeloid, nerve, osseous, reticular, scar, sclerous, skeletal, splenic, subcutaneous), tissue masses (e.g. tumors), etc.

Although the above description is given with respect to specific bipolar and monopolar devices disclosed herein, it should be readily appreciated that devices according to the present invention may be constructed and arranged to grasp, hold, fix, cut, dissect, expose, remove, extract, retrieve, and otherwise manipulate and treat organs, tissues, tissue masses, and objects.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications can be made therein without departing from the spirit of the invention and the scope of the appended claims. The scope of the invention should, therefore, be determined not with reference to the above description, but instead should be determined with reference to the appended claims along with their full scope of equivalents. Furthermore, it should be understood that the appended claims do not necessarily comprise the broadest scope of the invention which the Applicant is entitled to claim, or the only manner(s) in which the invention may be claimed, or that all recited features are necessary.

We claim:

1. A system for treating tissue comprising:
power from a power source at a power level;
a fluid from a fluid source at a fluid flow rate;
a surgical device which provides the power and the fluid simultaneously to treat the tissue; and
a control system which changes the fluid flow rate between at least two non-zero fluid flow rates and changes the power level between at least two non-zero levels.

2. The system for treating tissue according to claim 1 wherein:
the control system increases the fluid flow rate with an increase in the power level; and
the control system decreases the fluid flow rate with a decrease in the power level.

3. The system for treating tissue according to claim 1 wherein:
the power provided from the surgical device leads to a heating of at least a portion of the fluid provided from the surgical device; and
the heating of the fluid results in a property change of at least a portion of the fluid.

4. The system for treating tissue according to claim 3 wherein the property change of the fluid comprises a color change.

5. The system for treating tissue according to claim 3 wherein the property change of the fluid comprises a phase change from a liquid phase to a vapor phase.

6. The system for treating tissue according to claim 1 wherein:
the power provided from the surgical device leads to a heating of at least a portion of the fluid provided from the surgical device; and
the heating of the fluid results in vaporization of at least a portion of the fluid.

7. The system for treating tissue according to claim 6 wherein:
the control system increases or decreases the fluid flow rate with an increase or decrease in a boiling percentage of the fluid, respectively.

8. The system for treating tissue according to claim 7 wherein:
the power leads to a heating of the tissue; and
the vaporization of the fluid provides a temperature control mechanism for the heating of the tissue.

9. The system for treating tissue according to claim 8 wherein:
the fluid has a first heat of vaporization, and
the temperature control mechanism comprises the first heat of vaporization.

10. The system for treating tissue according to claim 1 wherein:
the control system further comprises a fluid flow rate controller and power source output measurement device; and
the fluid flow rate controller provides an output signal to change the fluid flow rate as a result of a change in an input signal received from the power source output measurement device signifying a change in the power level.

11. The system according to claim 1 wherein the power comprises radio frequency power.

12. The system according to claim 1 wherein the fluid source comprises an intravenous bag of fluid.

13. The system according to claim 1 wherein the fluid comprises one of an electrically conductive fluid and an electrically non-conductive fluid.

14. The system according to claim 1 wherein the control system comprises:
a fluid flow control mechanism for increasing and decreasing the fluid flow rate;
a power control mechanism for increasing and decreasing the power level provided from the surgical device; and
the fluid flow control mechanism increasing the fluid flow rate when the power control mechanism increases the power level, and the fluid flow control mechanism decreasing the fluid flow rate when the power control mechanism decreases the power level.

15. The system according to claim 14 wherein the fluid flow control mechanism comprises a manually activated device, and the power control mechanism comprises a manually activated device.

16. The system according to claim 15 wherein the manually activated device of the fluid flow control mechanism comprises at least one of a flow rate controller, a roller clamp, and a pump.

17. The system according to claim 15 wherein the manually activated device of the power control mechanism comprises a power selector switch of the power source.

18. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning as an indicator of tissue temperature.

19. The system for treating tissue according to claim 18 wherein the fluid coupling functions as an indicator of tissue temperature by boiling.

20. The system for treating tissue according to claim 18 wherein the fluid coupling functions as an indicator of tissue temperature by an amount of boiling.

21. The system for treating tissue according to claim 18 wherein the fluid coupling functions as an indicator of tissue temperature by using an onset of boiling of the fluid coupling.

22. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning to cool the tissue.

23. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning to dissipate heat from the tissue.

24. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning to dissipate heat from at least one of the tissue and the fluid coupling by a boiling of at least a portion of the fluid coupling.

25. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

at least one of the radio frequency power level and the conductive fluid flow rate used to effect a boiling of the fluid coupling.

26. The system for treating tissue according to claim 25 wherein at least one of the radio frequency power level and the conductive fluid flow rate used to effect a boiling of the fluid coupling comprises the effect of at least one of initiating, increasing, decreasing and eliminating boiling of the fluid coupling.

27. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning to limit the temperature of the tissue at the tissue surface to about a boiling temperature of the fluid coupling.

28. A system for treating tissue comprising:

radio frequency power provided from a power source at a power level;

an electrically conductive fluid provided from a fluid source at a fluid flow rate;

an electrosurgical device configured to provide the radio frequency power with the electrically conductive fluid to the tissue;

a fluid coupling comprising the electrically conductive fluid which couples the tissue and the electrosurgical device; and

the fluid coupling functioning to protect the tissue from desiccation.

29. The system for treating tissue according to claim 28 wherein the fluid coupling functioning to protect the tissue from desiccation further comprises:

the fluid coupling functioning to protect the tissue from desiccation by boiling at least a portion of the fluid coupling.

30. The system for treating tissue according to claim 29 wherein the fluid coupling functioning to protect the tissue from desiccation by boiling at least a portion of the fluid coupling further comprises:

the fluid coupling functioning to protect the tissue from desiccation by boiling at least a portion of the fluid coupling at a temperature which protects the tissue from desiccation.

31. A surgical device for treating tissue comprising:

a first jaw and a second jaw forming a device jaw;

a fluid delivery passage passing through each jaw;

the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming the fluid delivery passage passing through the first jaw;

the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming the fluid delivery passage passing through the second jaw; and

at least one fluid exit opening provided with each jaw, the fluid exit opening being in communication with the fluid delivery passage passing through the jaw; and

at least a portion of each jaw comprising a porous material, the porous material comprising at least one porous material fluid inlet surface and at least one porous material fluid outlet surface, the fluid inlet surface and the fluid outlet surface connected by a plurality of tortuous pathways in the porous material.

32. A surgical device for treating tissue comprising:

a first jaw and a second jaw forming a device jaw;

an output related to a magnitude of tissue within the device jaw, the output configured to provide at least one of an estimated tissue treatment time for the tissue and a measurement on a measurement scale.

33. The surgical device according to claim 32 wherein:

the measurement scale is located on the surgical device.

34. A surgical device for treating tissue comprising:

a first jaw and a second jaw forming a device jaw;

a fluid delivery passage passing through each jaw;

the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming the fluid delivery passage passing through the first jaw;

the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming the fluid delivery passage passing through the second jaw; and

at least one fluid exit opening provided with each jaw, the fluid exit opening being in communication with the fluid delivery passage passing through the jaw; and

a fluid application mechanism which directs application of the a fluid provided from each jaw only to a portion of each jaw occupied by tissue.

35. A surgical device for treating tissue having a proximal end and a distal end, the device comprising:

a first jaw and a second jaw forming a device jaw;

a fluid delivery passage passing through each jaw;

the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming the fluid delivery passage passing through the first jaw and the first electrode outer surface providing a portion of a first jaw tissue grasping surface;

the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming the fluid delivery passage passing through the second jaw and the second electrode outer surface providing at least a portion of a second jaw tissue grasping surface; and

at least one fluid exit opening provided with each jaw, the fluid exit opening being in communication with the fluid delivery passage, the fluid exit opening positioned to direct fluid from the fluid delivery passage proximally.

36. A surgical device for treating tissue comprising:

a first jaw and a second jaw forming a device jaw;

a fluid delivery passage passing through each jaw;

the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming the fluid delivery passage passing through the first jaw and the first electrode outer surface providing a portion of a first jaw tissue grasping surface;

the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming the fluid delivery passage passing through the second jaw and the second electrode outer surface providing at least a portion of a second jaw tissue grasping surface; and

at least one fluid exit opening provided with each jaw, the fluid exit opening being in communication with the fluid delivery passage, the fluid exit opening remote from the jaw tissue grasping surface.

37. A surgical device for treating tissue comprising:

a first jaw and a second jaw forming a device jaw;

a fluid delivery passage passing through each jaw;

at least one fluid exit opening provided with each jaw, the fluid exit opening being in communication with the fluid delivery passage;

the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming the fluid delivery passage passing through the first jaw;

the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming the fluid delivery passage passing through the second jaw;

the first jaw having a first jaw tissue grasping surface, the first jaw tissue grasping surface comprising an outer electrically insulated U-shaped tissue grasping surface, an inner electrically insulated U-shaped tissue grasping surface and the first electrode outer surface, the first electrode outer surface located between the outer U-shaped tissue grasping surface and the inner U-shaped tissue grasping surface; and

the second jaw having a second jaw tissue grasping surface, the second jaw tissue grasping surface comprising an outer electrically insulated U-shaped tissue grasping surface, an inner electrically insulated U-shaped tissue grasping surface and the second electrode outer surface, the second electrode outer surface located between the outer U-shaped tissue grasping surface and the inner U-shaped tissue grasping surface.

38. The surgical device according to claim 37 wherein:

the first jaw outer electrically insulated U-shaped tissue grasping surface is beveled relative to the first electrode surface; and

the second jaw outer electrically insulated U-shaped tissue grasping surface is beveled relative to the second electrode surface.

39. A method of treating tissue comprising:

providing a first jaw, the first jaw having a first electrode, the first electrode having an inner surface and an outer surface, the first electrode inner surface at least partially forming a fluid delivery passage passing through the first jaw;

providing a second jaw, the second jaw having a second electrode, the second electrode having an inner surface and an outer surface, the second electrode inner surface at least partially forming a fluid delivery passage passing through the second jaw;

forming a device jaw with the first jaw and the second jaw, the first jaw and second jaw hinged relative to one another;

grasping tissue within the device jaw, the tissue grasped with the first electrode outer surface and the second electrode outer surface;

providing radio frequency power from the first and second electrodes to the tissue;

sealing the tissue against at least one of the flow of bodily fluids and air; and

cooling at least one of the tissue and the electrodes with an electrically non-conductive fluid.

40. The method according to claim 39 wherein:
the tissue comprises lung.

41. A method for aerostasis of a tissue comprising:
providing an electrosurgical forceps device having a device jaw;
providing an electrically non-conductive fluid and electrical energy from the device jaw; and
providing the fluid in rate and the electrical energy in power sufficient to seal the tissue against air flow from the tissue while grasping the tissue with the device jaw.

FIG. 1

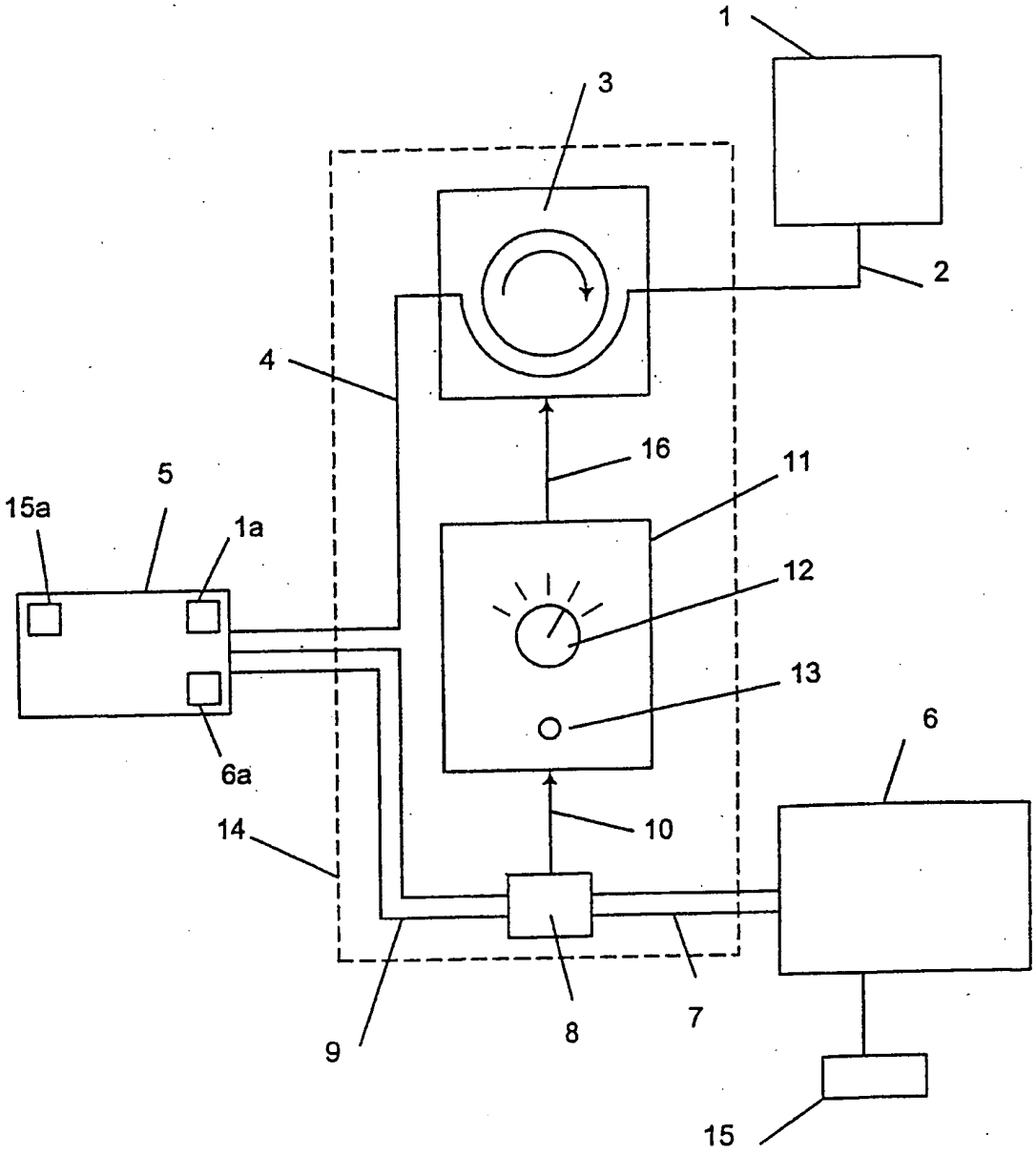


FIG. 2

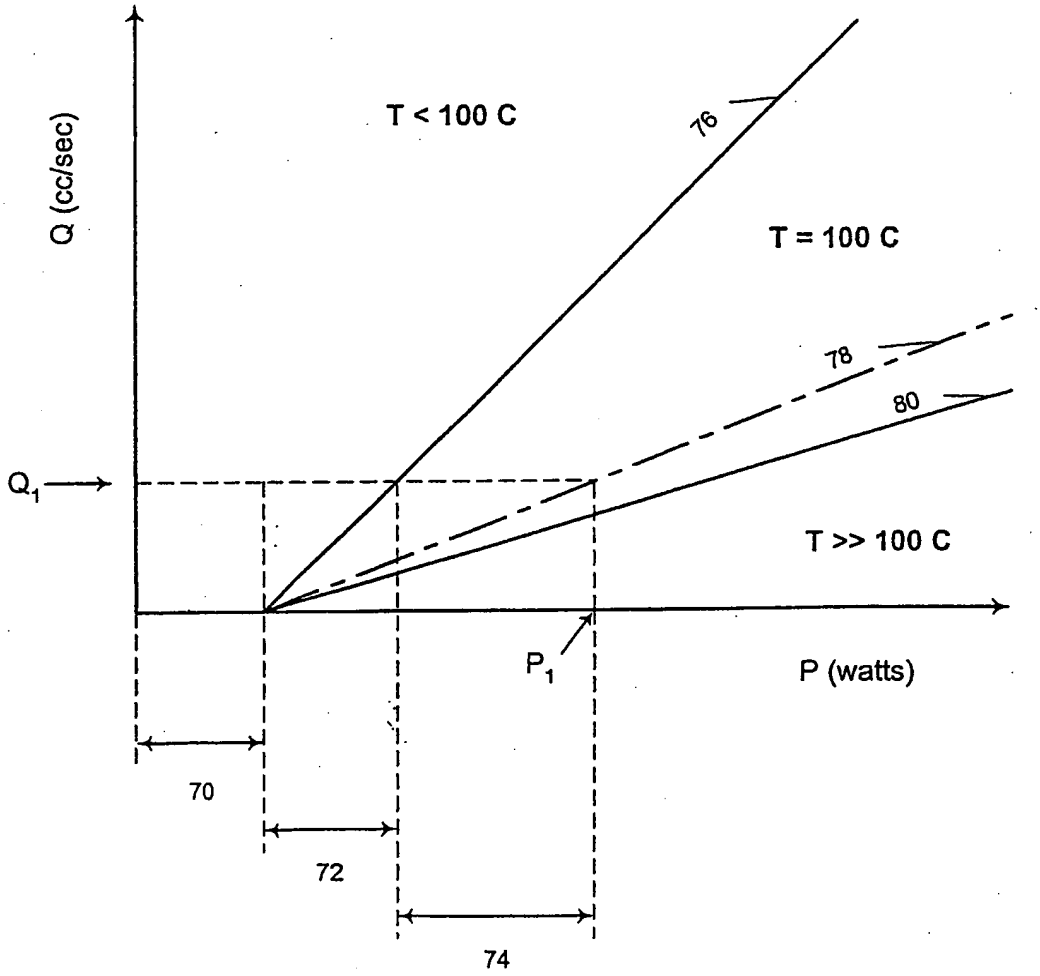


FIG. 3

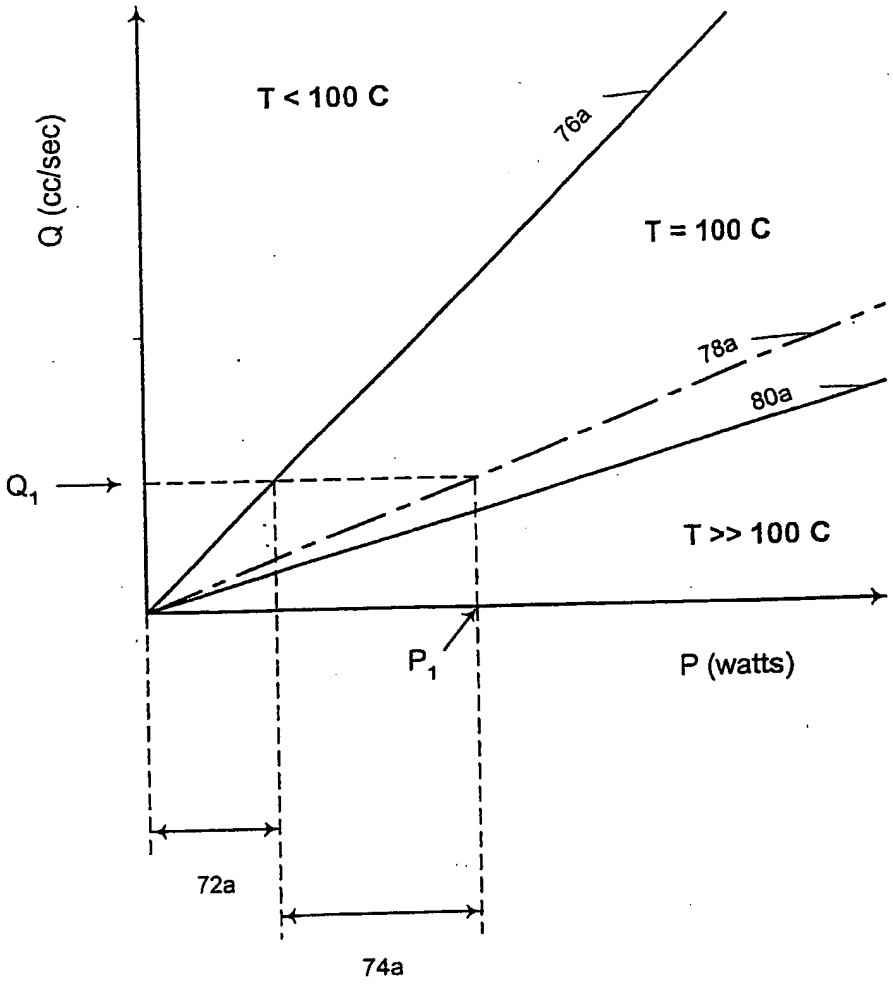


FIG. 4

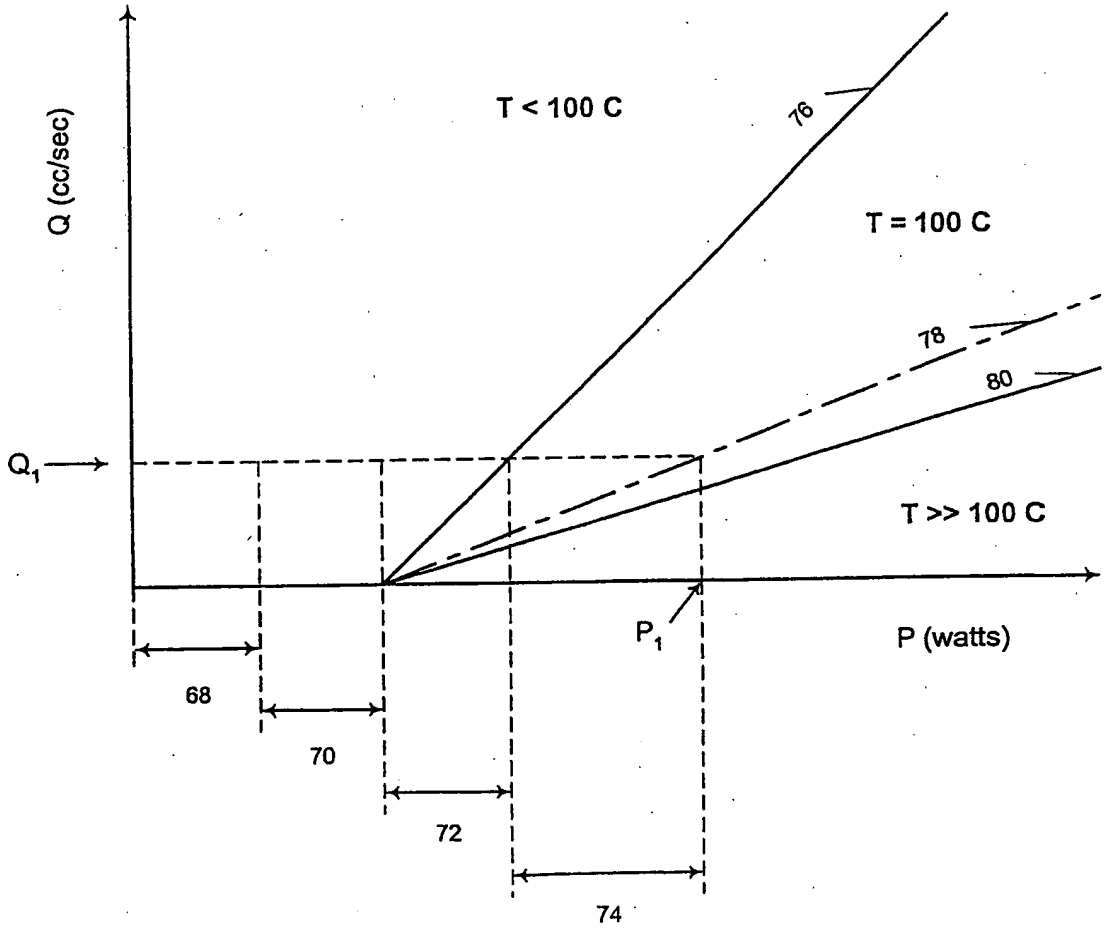


FIG. 5

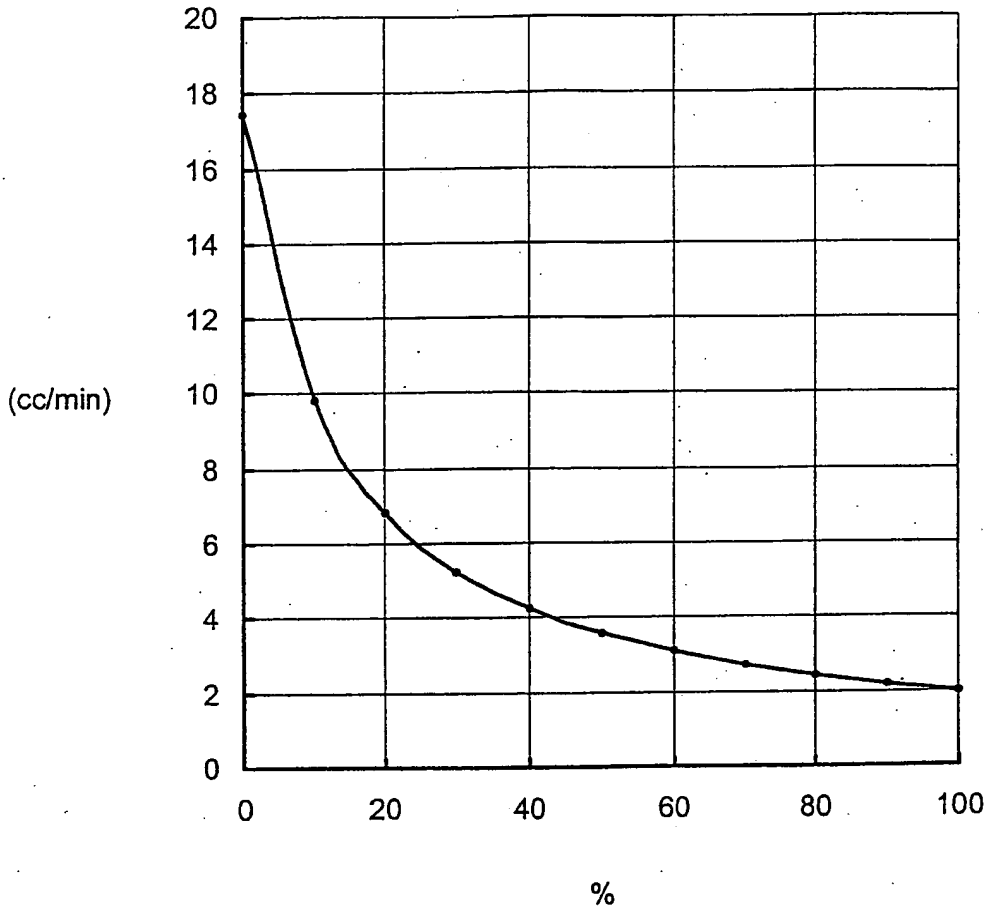


FIG. 6

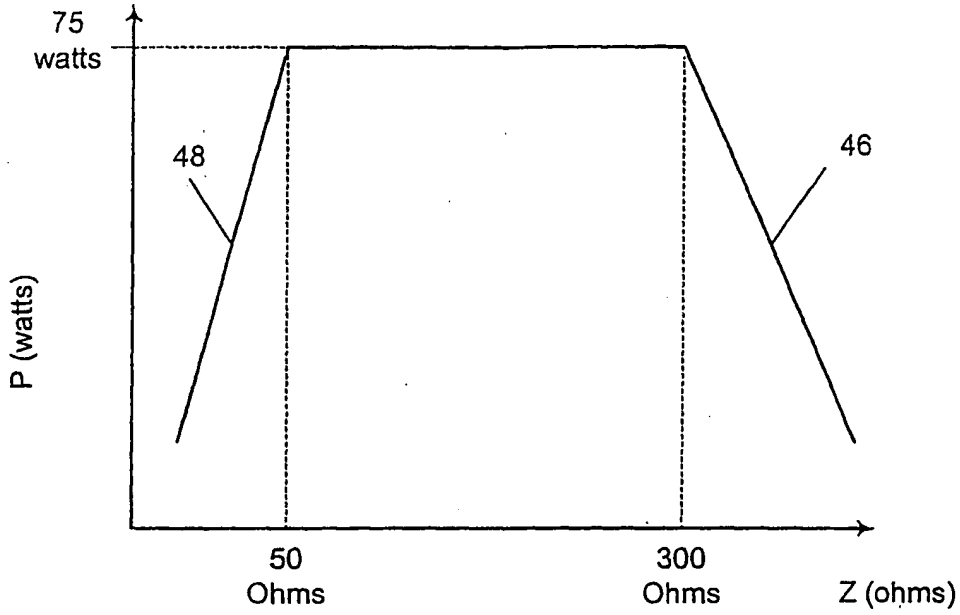


FIG. 7

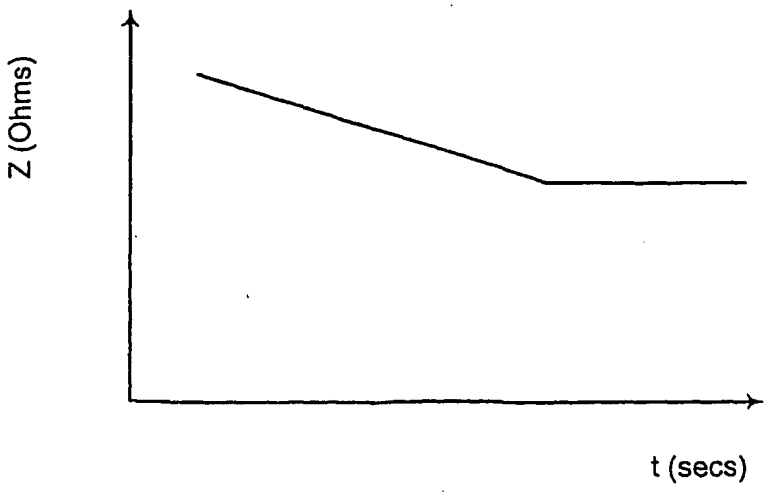


FIG. 8

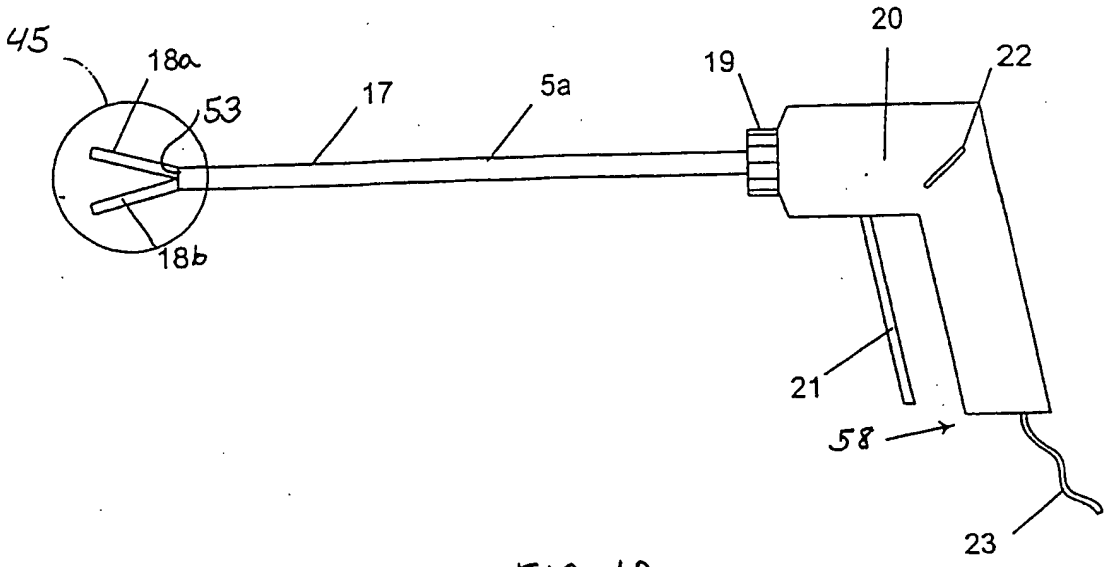
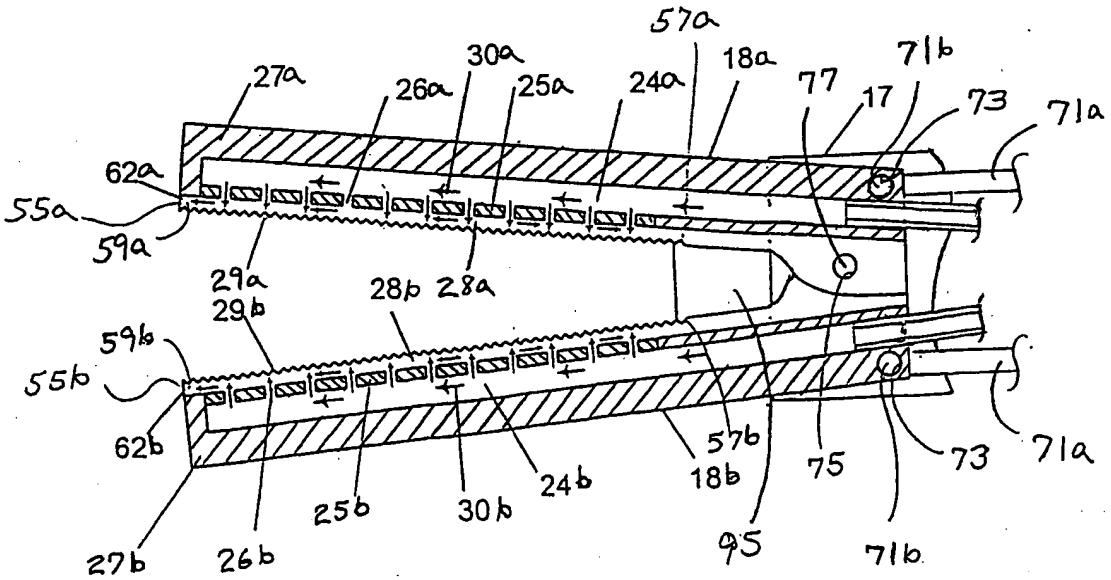

45
18a
53
17
5a
19
20
22
18b
21
58
23

FIG. 10


57a
27a
30a
26a
25a
24a
18a
77
71b
17
73
71a
62a
55a
59a
29a
29b
28b
28a
59b
55b
62b
57b
18b
75
73
71a
24b
25b
30b
27b
26b
95
71b

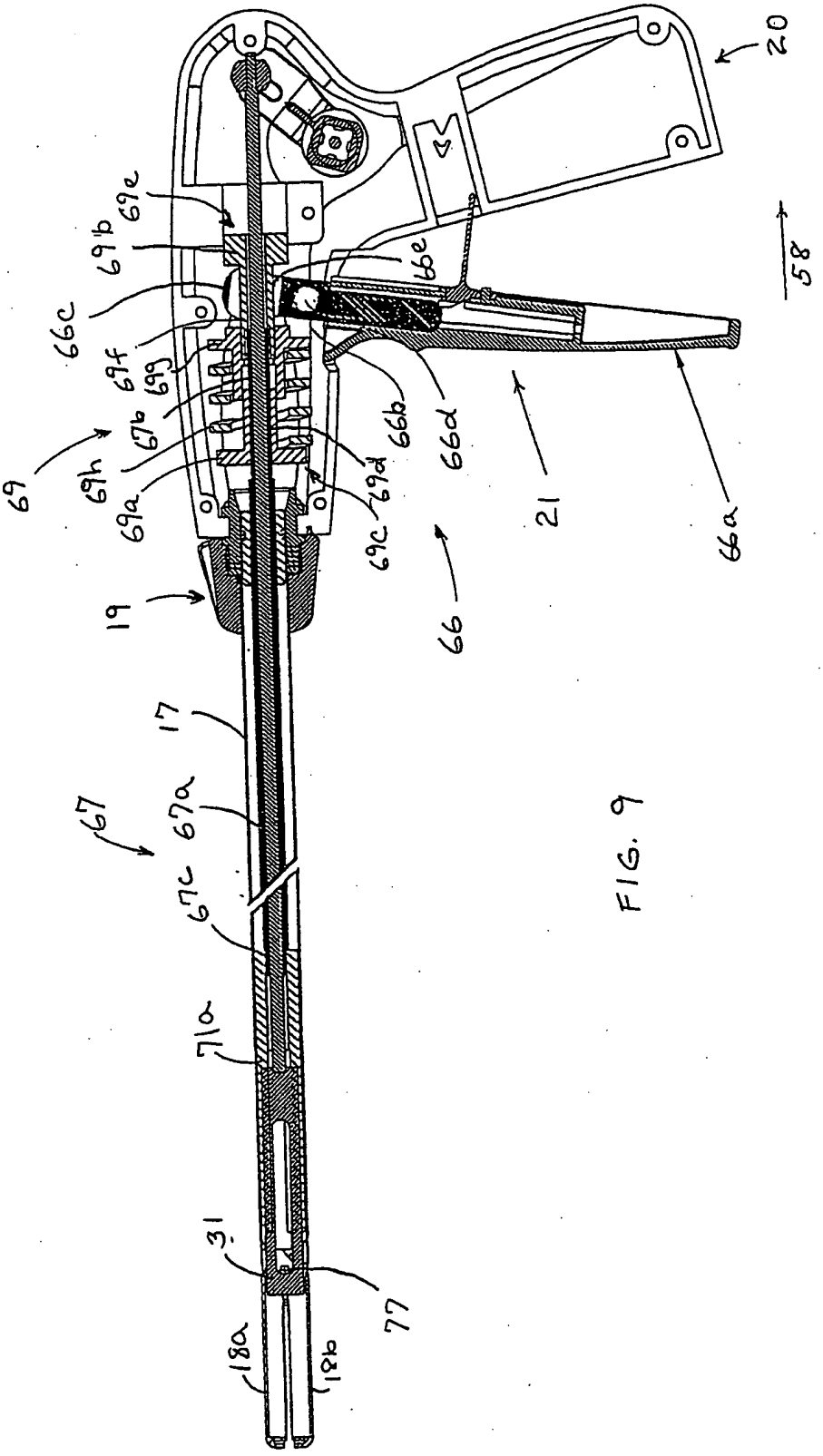

20
58
69e
69b
66e
66c
69f
69g
69
69h
69a
67b
69d
66b
66d
21
66a
69c
66
19
17
67
67a
67c
710a
31
77
180a
181a

FIG. 9

FIG. 11

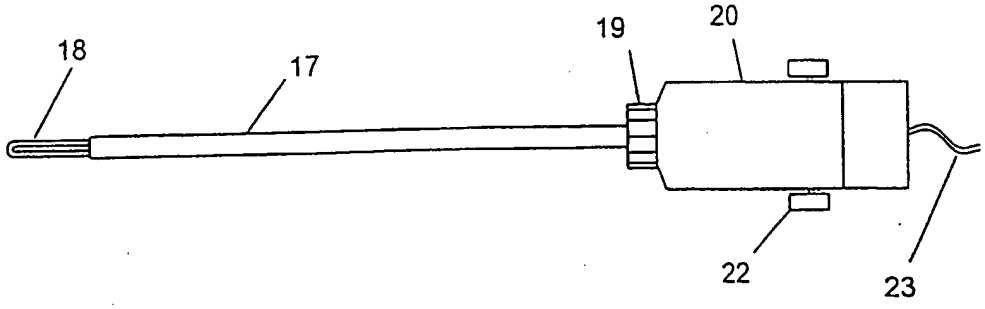

18
17
19
20
22
23

FIG. 12

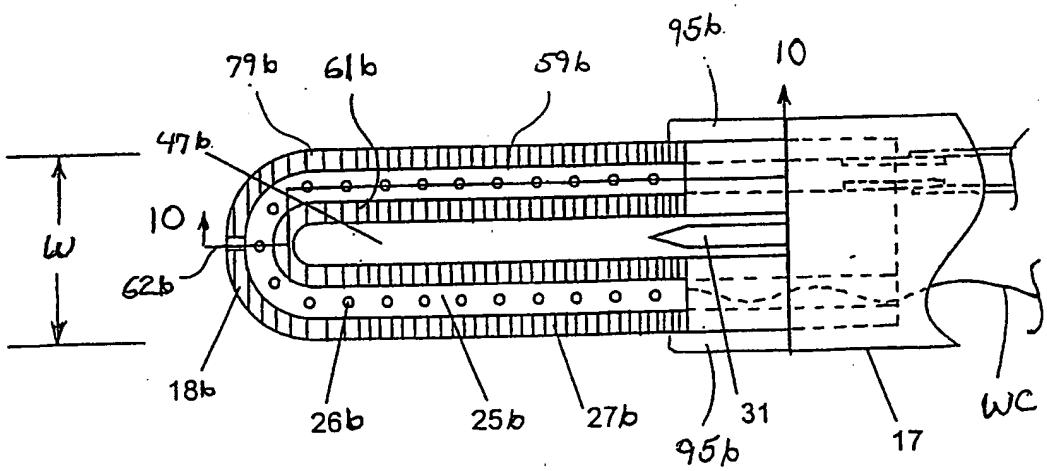

79b
61b
59b
95b
10
47b
10
W
62b
18b
26b
25b
27b
95b
31
17
WC

FIG. 13

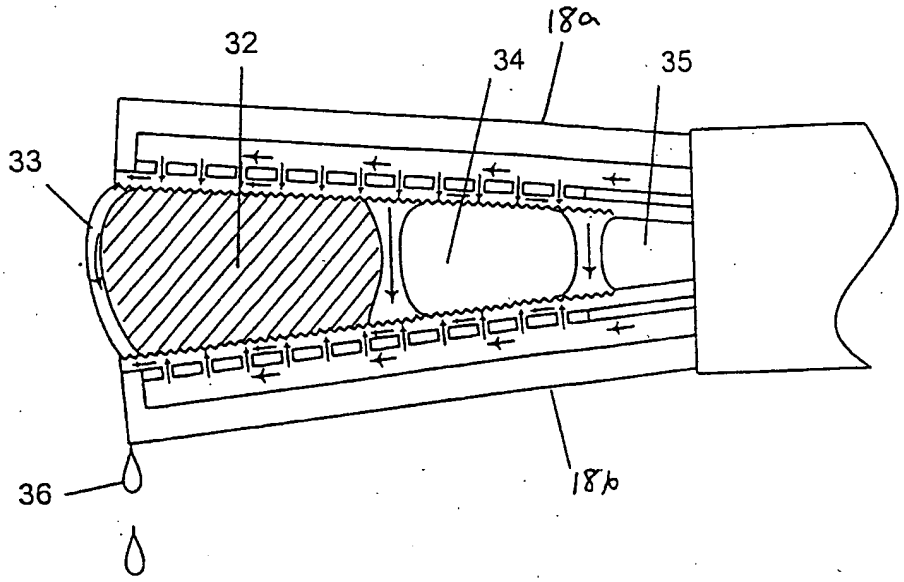


FIG. 16

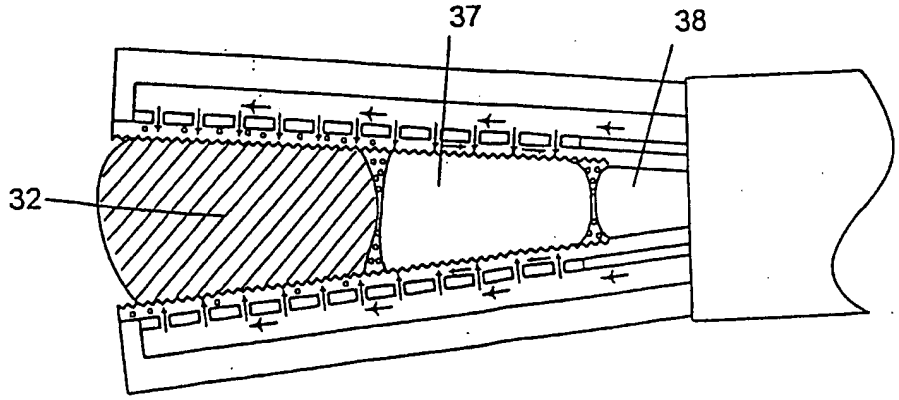


FIG. 14

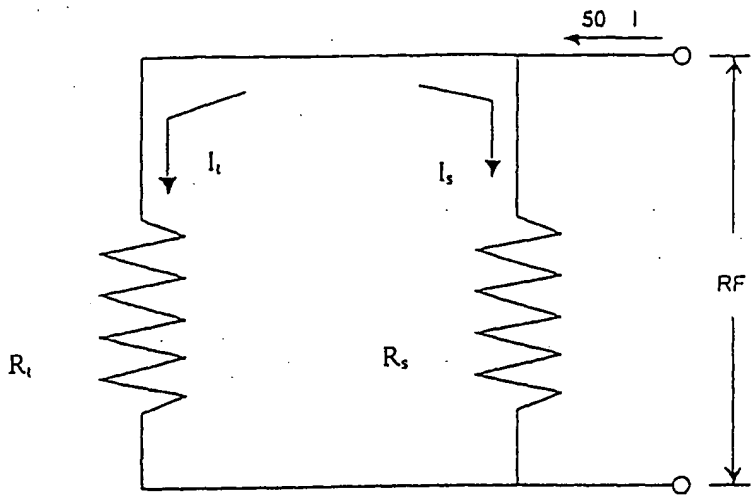


FIG. 15

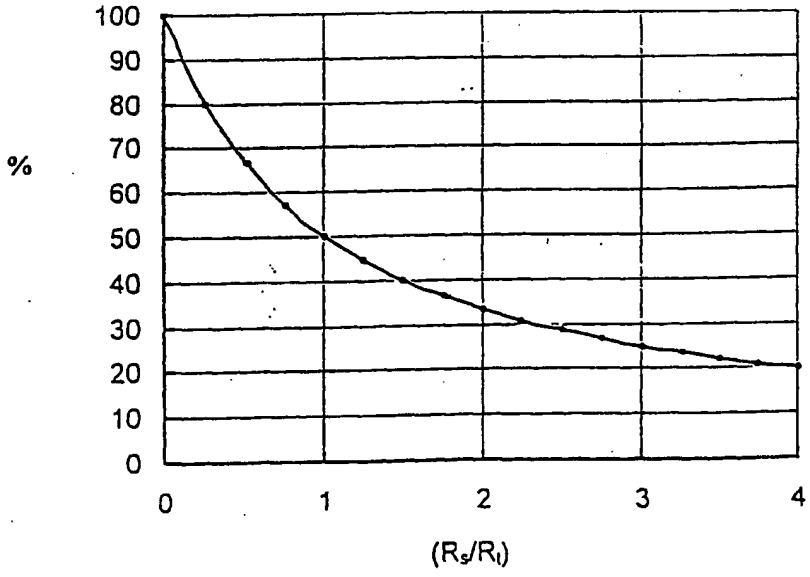


FIG. 17

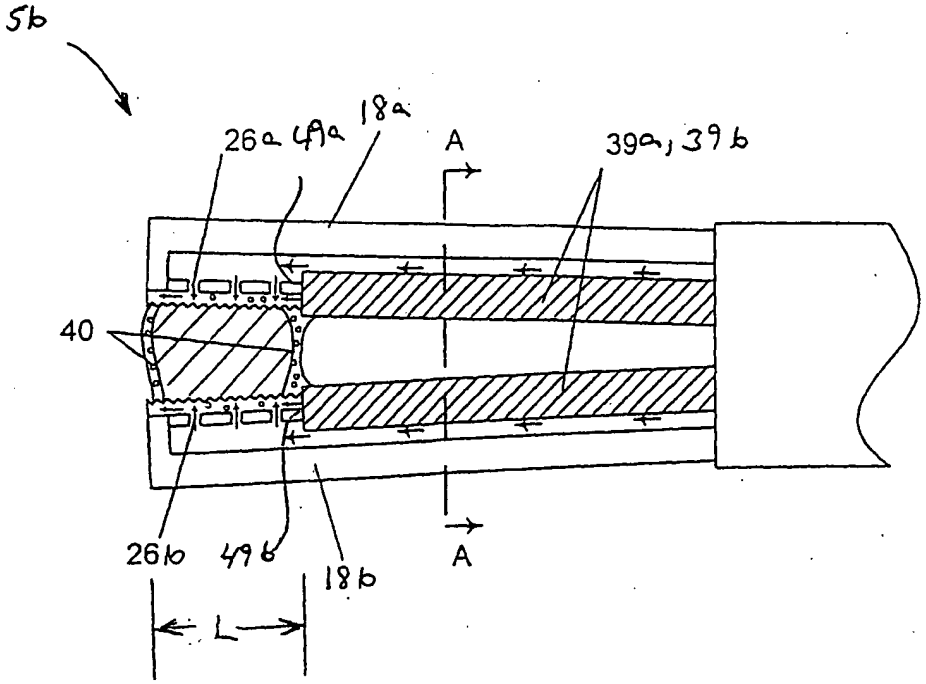

5b
26a
49a
18a
A
39a, 39b
40
26b
49b
18b
A
L

FIG. 18

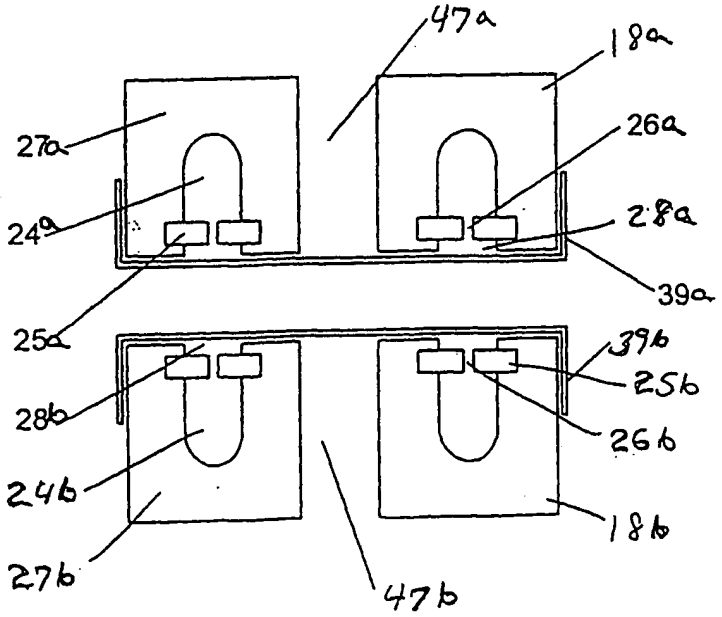

47a
18a
27a
26a
24a
28a
39a
25a
39b
25b
28b
26b
24b
18b
27b
47b

FIG. 19

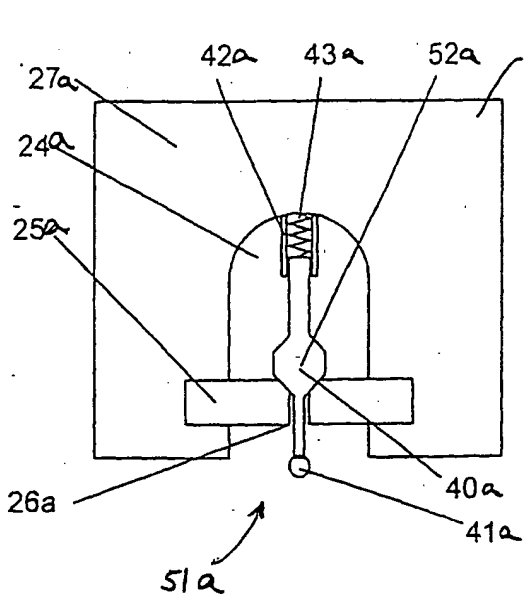


FIG. 20

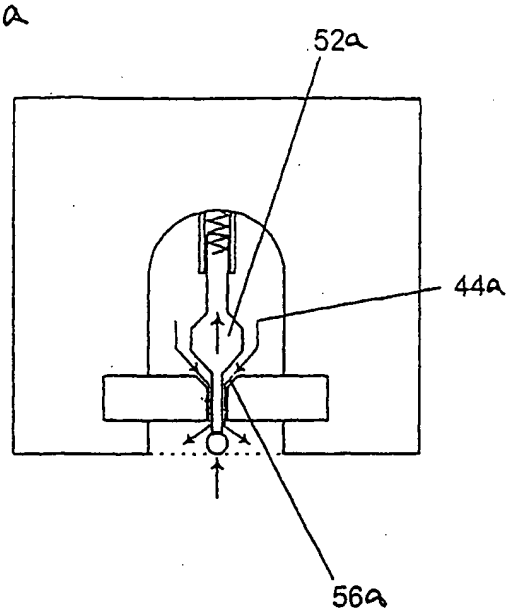


FIG. 21

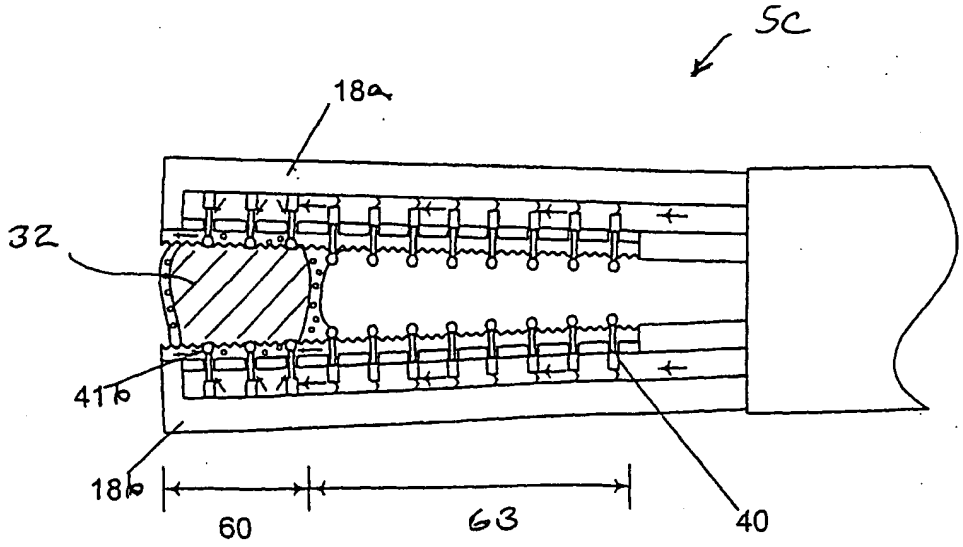


FIG. 22

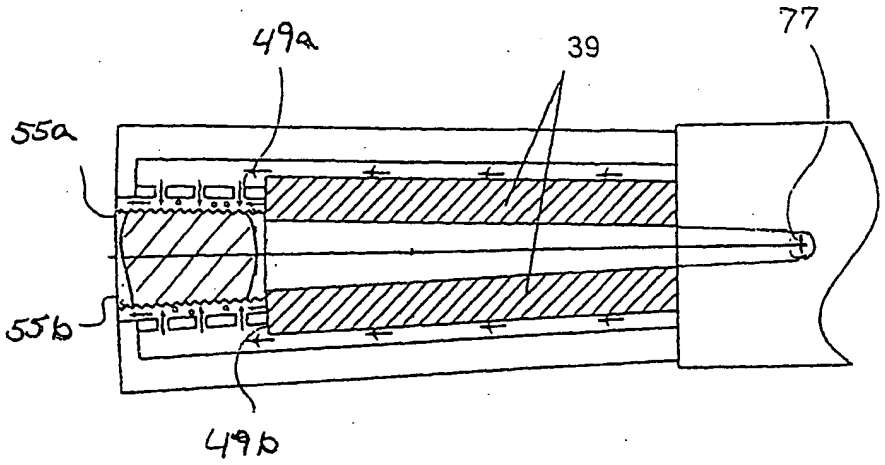


FIG. 25

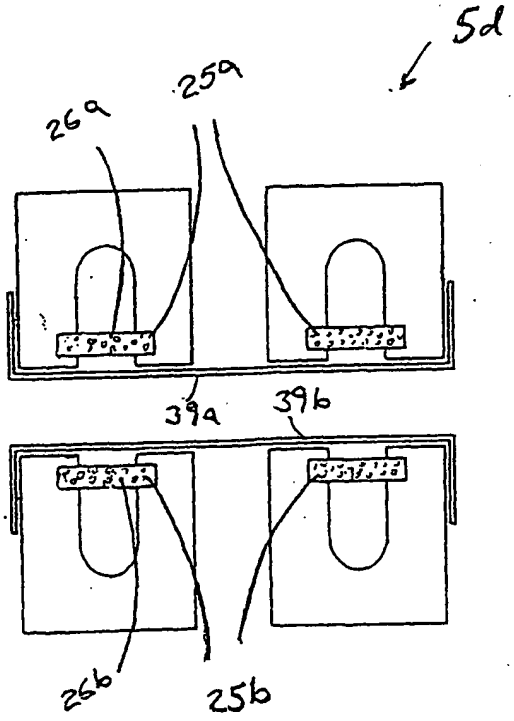


FIG. 23

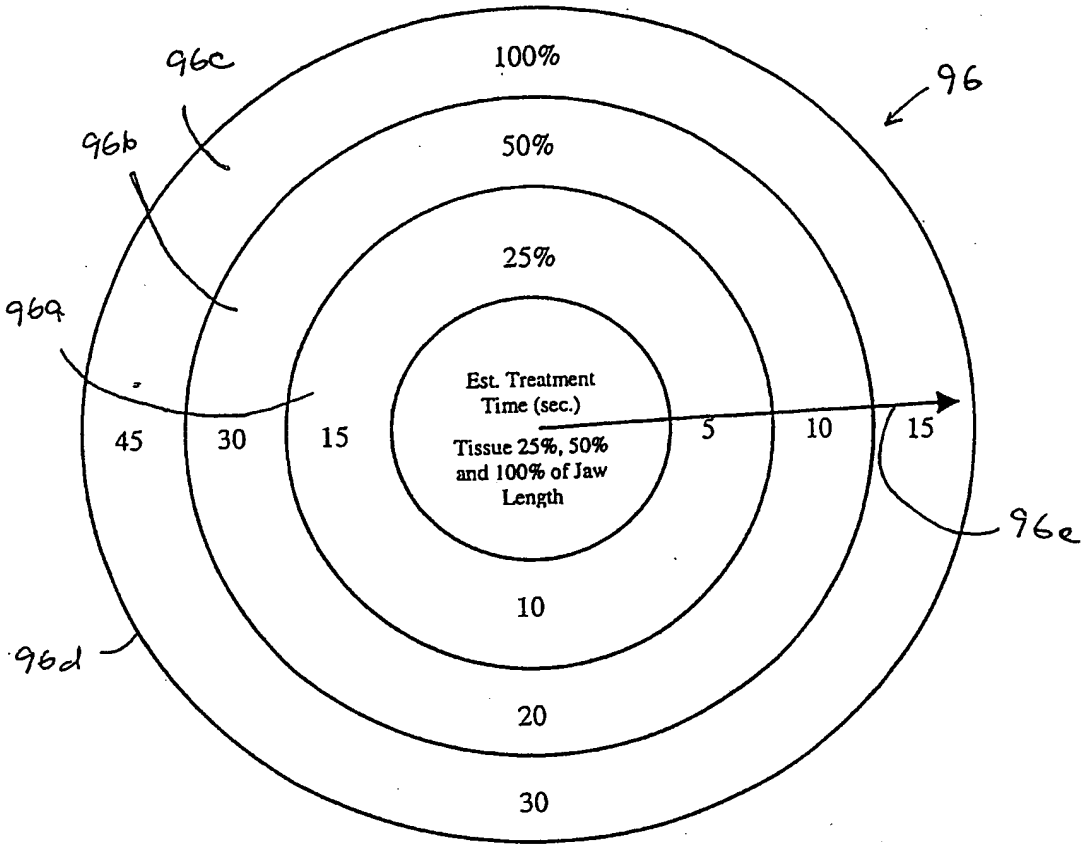

96c
96
96b
100%
50%
25%
96a
Est. Treatment Time (sec.)
Tissue 25%, 50% and 100% of Jaw Length
45
30
15
5
10
15
96e
10
96d
20
30

FIG. 24

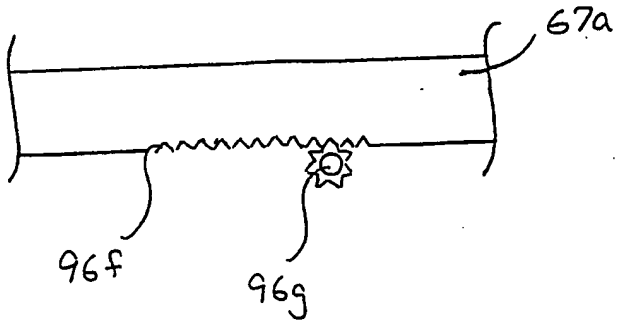
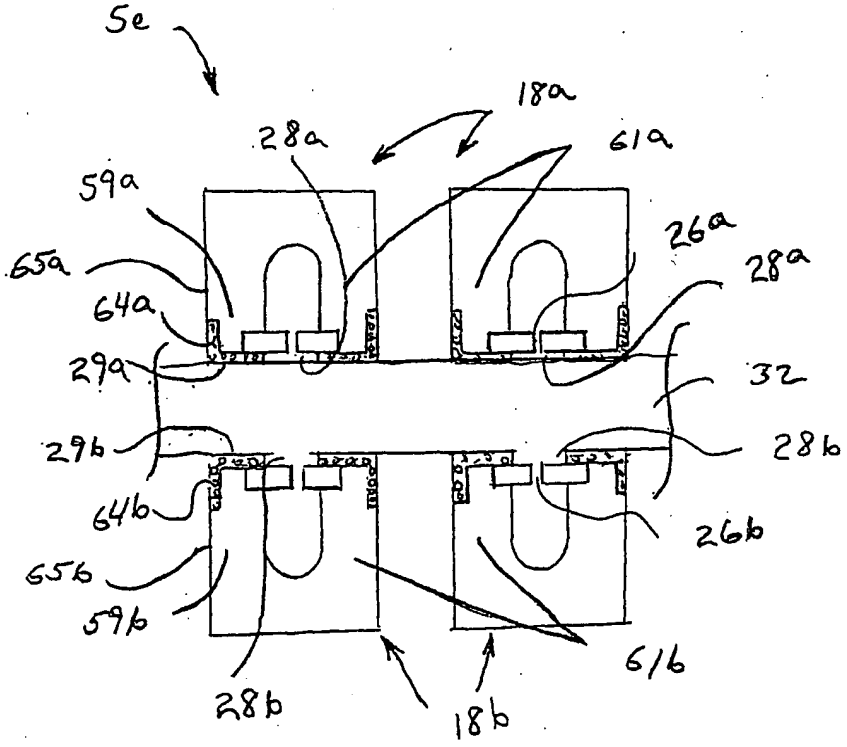

67a
96f
96g

FIG. 26


5e
18a
28a
61a
59a
26a
65a
28a
64a
29a
32
29b
28b
64b
26b
65b
59b
61b
28b
18b

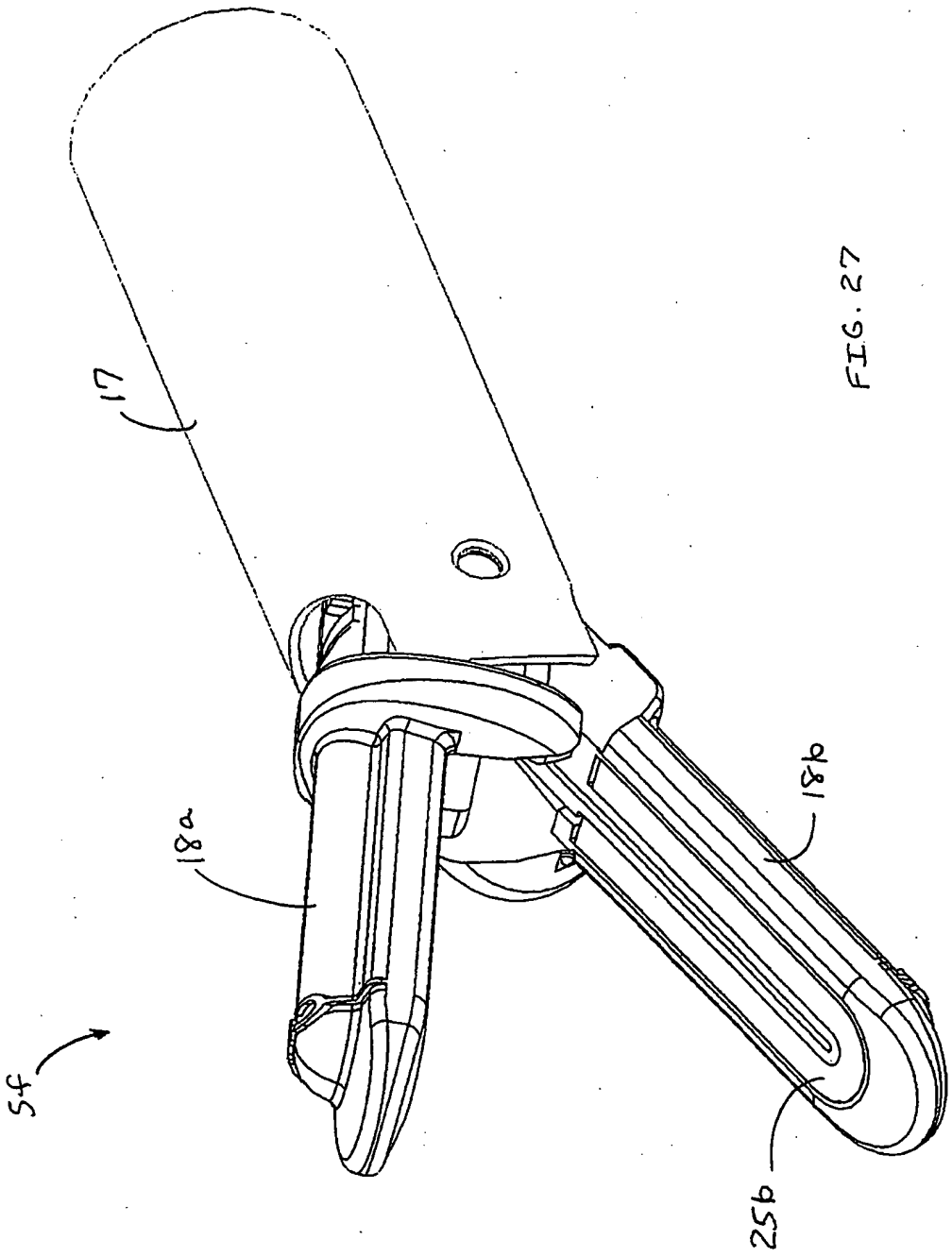


FIG. 27

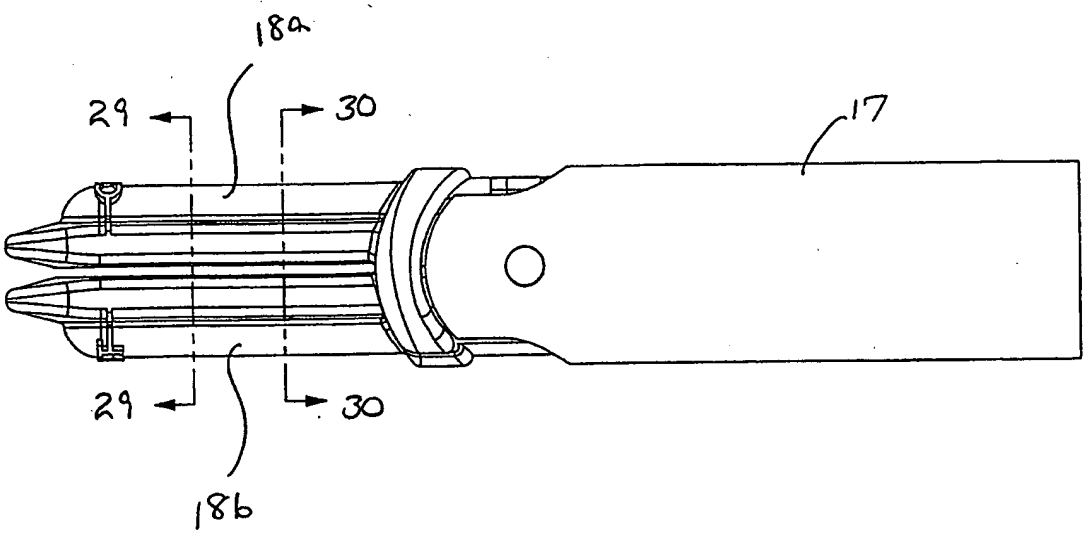


FIG. 28

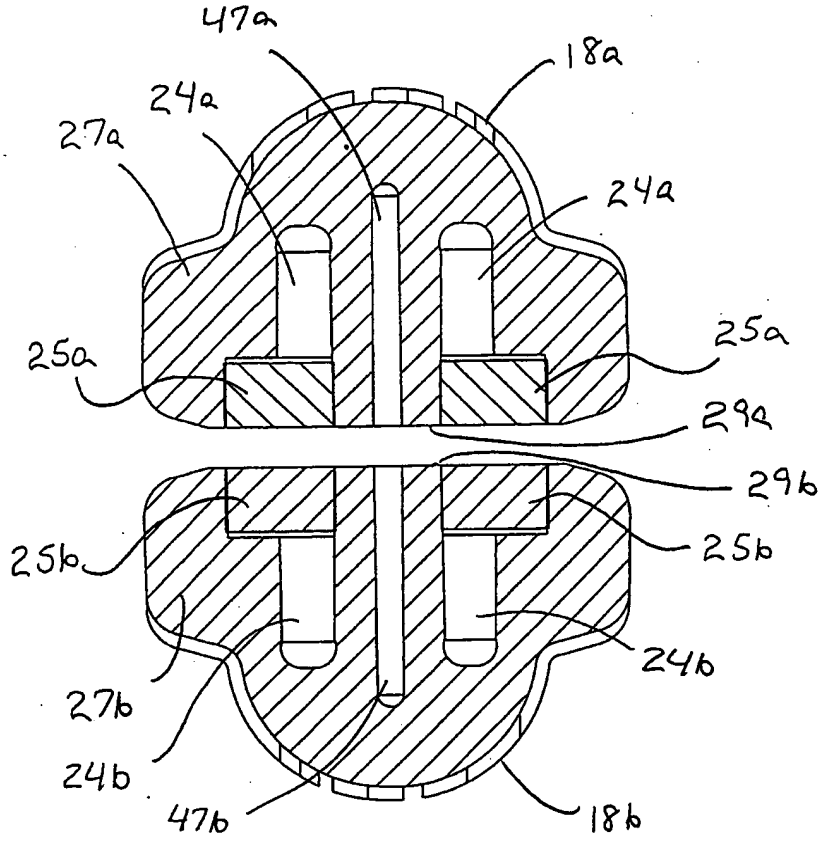


FIG. 29

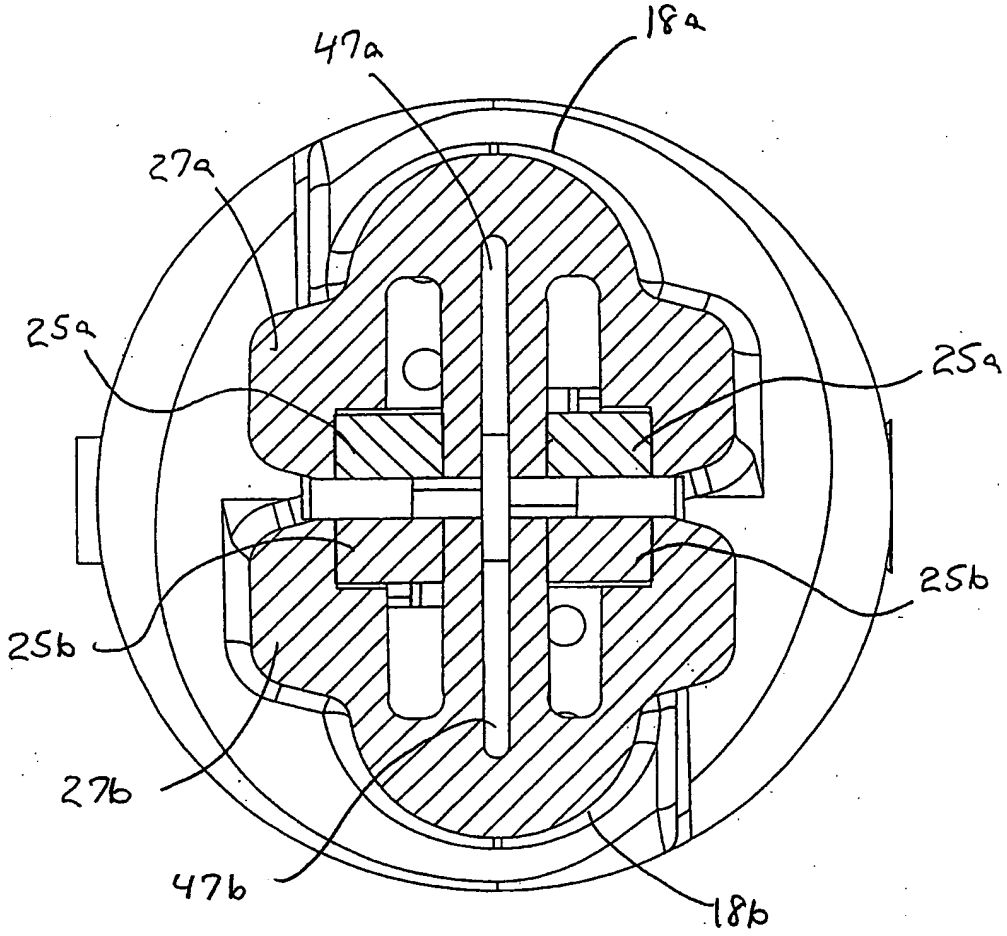


FIG. 30

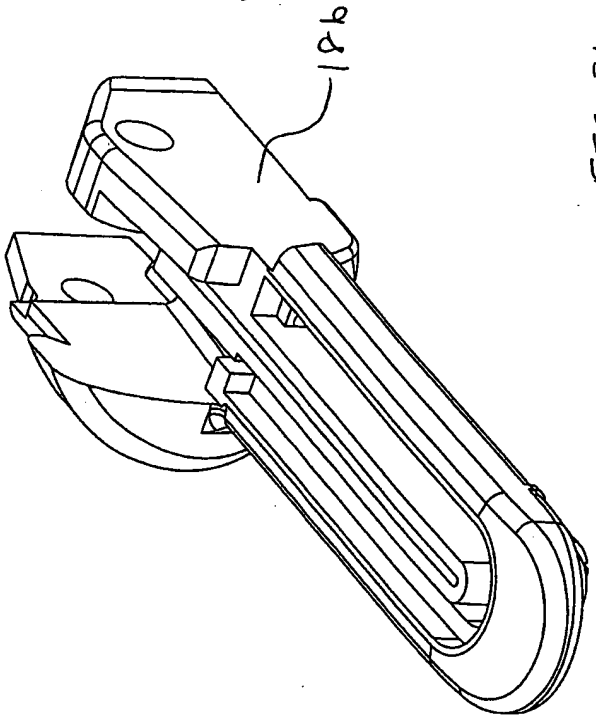


FIG. 31

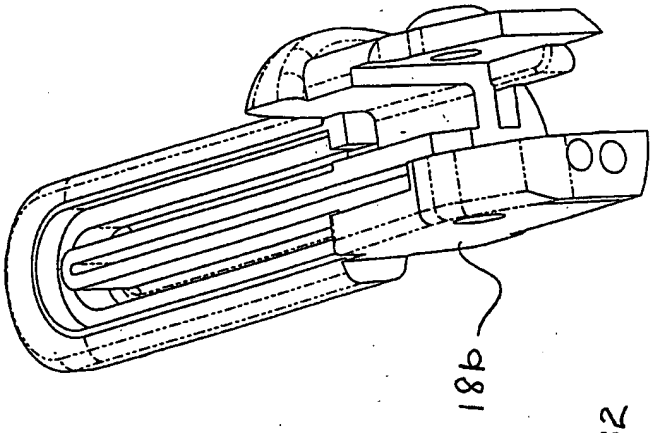


FIG. 32